EFFECTIVENESS OF CRYOTHERAPY ON PROCEDURAL PAIN AMONG THE CARDIAC POST OPERATIVE PATIENTS AT A SELECTED SETTING IN CHENNAI

Dissertation submitted to

THE TAMIL NADU Dr.M.G.R.MEDICAL UNIVERSITY

CHENNAI

In partial fulfilment of requirement for the degree of

MASTER OF SCIENCE IN NURSING

APRIL 2016

EFFECTIVENESS OF CRYOTHERAPY ON PROCEDURAL PAIN AMONG THE CARDIAC POST OPERATIVE PATIENTS AT A SELECTED SETTING IN CHENNAI

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LIST OF ABBREVIATIONS

AHA	-	American Heart Association
AHI	-	Asian Heart Institute
AICU	-	Adult Intensive Care Unit
APA	-	American Pain Association
APS	-	American Pain Society
BMI	-	Body Mass Index
BP	-	Blood Pressure
CABG	-	Coronary Artery Bypass Graft
CAD	-	Coronary Artery Disease
CPOT	-	Critical Care Pain Observation Tool
CTR	-	Chest Tube Removal
CVD	-	Cardio Vascular Disease
CXR	-	Chest X Ray
EPW	-	Epicardial Pacing Wire
FLACC	-	Faces Legs Activity Cry Consolability Scale
HR	-	Heart Rate
ICU	-	Intensive Care Units
JCAHO	-	Joint Commission for Accreditation of Health Care Organization
MI	-	Myocardial Infarction
MIDHAS	-	Minimally Invasive Direct Heart Access Surgery
MMM	-	Madras Medical Mission
MSFQ	-	McGill Short Form Questionnaire
MVR	-	Mitral Valve Replacement
NCV	-	Nerve Conduction Velocity
NSAIDs	-	Non Steroidal Anti Inflammatory Drugs
NVPS	-	Non Verbal Pain Scale
OT	-	Operation Theatre
PCA	-	Patient Controlled Analgesia
PCI	-	Percutaneous Coronary Intervention
POD	-	Post Operative Day
PTH	-	Pain Threshold

PTO	-	Pain Tolerance
QRT	-	Quick Relaxation Technique
RR	-	Respiratory Rate
SD	-	Standard Deviation
SpO_2	-	Saturation of Peripheral Oxygen
TTC	-	Trans Thoracic Cardioversion
USA	-	United States of America
VAP	-	Visual Analogue Pain Scale
VAS	-	Visual Analogue Scale
WHF	-	World Heart Federation
WHO	-	World Health Organization

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ABSTRACT

ABSTRACT

A study to assess the effectiveness of cryotherapy on procedural pain among cardiac post operative patients at a selected setting in Chennai

OBJECTIVES

1. To assess the baseline and post test level of procedural pain in experimental and control group.
2. To assess the effectiveness of cryotherapy on the level of procedural pain between the experimental and control group.
3. To associate the post test level of procedural pain with selected demographic and clinical variables of experimental group.

METHODOLOGY

The research design used was true experimental post test only design, the study was conducted in the post operative cardiac AICU of Madras Medical Mission hospital, Chennai. 80 samples were selected by using simple random sampling technique using lottery method in which 40 each was allotted to the experimental and control group. The experimental group had the cryotherapy (cooling gel pack) applied around the chest tube insertion site for 15 minutes prior to chest tube removal along with hospital routine (Inj.Perfelgan) 30minutes prior to the chest tube removal whereas in the control group, patients were administered only the usual hospital routine during chest tube removal. The data was collected by using modified comfort scale (pain distress) and visual analogue scale (pain intensity) 30 minutes before Chest Tube Removal (CTR), during CTR within 5minutes and 20 minutes after CTR. The data collected was organized and tabulated for analysis.

RESULTS

The overall statistical analysis in the experimental group revealed that in the post test I level of pain distress 26(65%) of them had severe pain distress and 14(40%) of them had very severe pain distress. The post test II level of pain distress showed that 34(85%) and 6(15%) of them in the experimental group had mild and moderate pain distress level respectively. Whereas the statistical analysis in the control group revealed

that the post test I level of pain distress 40(100%) of them had very severe pain distress and the post test II level of pain distress showed that 14(35%) and 26(65%) of them in the experimental group had mild and moderate pain distress level respectively.

The overall statistical analysis in the experimental group revealed that the post test I level of pain intensity 1(2.5%) of them had moderate pain intensity and 39(97.5%) of them had very severe pain intensity. The post test II level of pain intensity showed that 20(50%) and 20(50%) of them in the experimental group had mild and moderate pain respectively. Whereas the overall statistical analysis in the control group revealed that the post test I level of pain intensity 40(100%) of them had very severe pain intensity and the post test II level of pain intensity showed that 5(12.5%) and 35(87.5%) of them in the experimental group had mild and moderate pain intensity level respectively.

The results revealed that there was statistically significant difference in the level of pain distress between the experimental and control group in post test I at $p<0.05$ level of significance with a " t" value of 7.428 and for post test II at $p<0.05$ level of significance with a " t" value of 6.731. There was statistical significant difference in the level of pain intensity between the experimental and control group in post test I at $p<0.05$ level of significance with a " t" value of 4.737 and for post test II at $p<0.05$ level of significance with a " t" value of 4.606.

CONCLUSION

The study concluded that there was a significant difference i.e. reduction in level of procedural pain after cryotherapy (cooling gel pack) application prior to chest tube removal among cardiac post operative patients in the experimental group. Thus making CTR less complicated and less distressing for the patients and it heightens the need for effective post operative pain management among nurses working in ICU.

INTRODUCTION

CHAPTER – 1

INTRODUCTION

"Pain insists upon being attended to and if not with great pain comes great change."

— C.S. Lewis

1.1 BACKGROUND OF THE STUDY

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, according to **International Association for Study of Pain (2012)**. Pain is a universal human experience and the most common reason people seek medical care. Pain conveys us something is wrong in the structure or function of our body and that we need to do something about it. For the reason that pain is such a strong motivator for action, it is considered one of the body's most important protective mechanisms.

Pain is one of the major stressors for critically ill patients and is also a common symptom for most of them. Critically ill patients experience moderate to severe pain (Nelson et al., 2009). Diseases, traumas, endotracheal intubations, surgeries, examinations, and even routine medical procedures such as suctioning and turning can cause pain. If pain is not dealt within a proper and timely manner, both the physiological and psychological comfort of a patient will be negatively affected.

Moderate to severe postoperative pain is experienced by >80% of patients having surgery (Allred et al.,2012). Several studies have shown that hospitalized patients experience inadequate pain relief and report moderate to high pain scores (Sommer et al.,2010). Although pain is a predictable part of the post operative experience, inadequate management of pain is common and have profound negative implications on the clinical outcomes resulting in deep vein thrombosis; pulmonary embolism, coronary ischemia, myocardial infarction, pneumonia, poor wound healing, insomnia and demoralization (Apfelbaum et al.,2008).

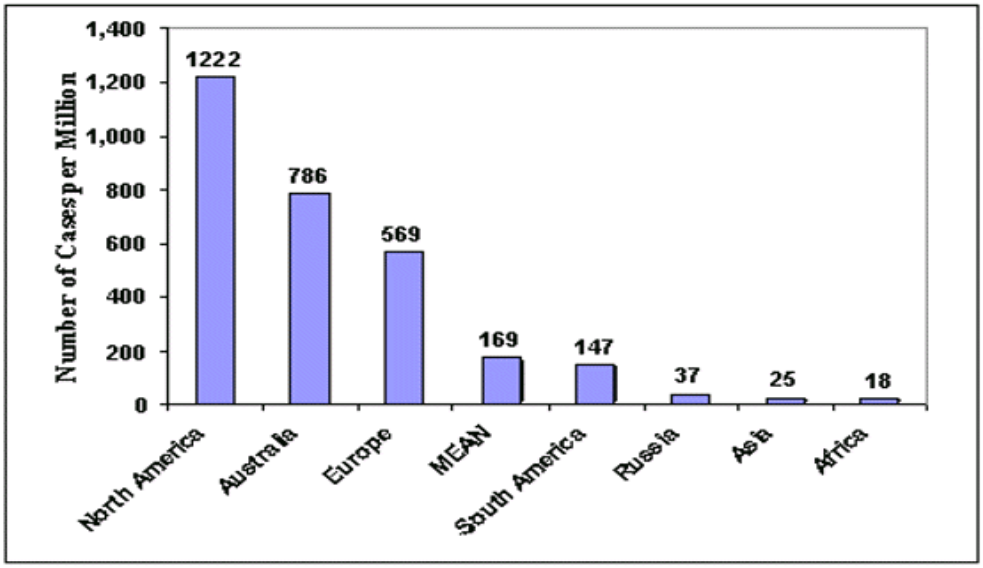

Fig.1.1.1: Total number of Cardio Vascular surgeries performed in the year 2013 globally.

Source: Annual report on Open Heart procedures: World Heart Federation 2013

According to the **World Heart Federation (WHF) report (2013)** nearly 1.5 million open-heart operations were done in the year 2013 worldwide and out of which 1,222 open-heart operations per million population were done in North America, compared to 18 per million in Africa. In Europe 569 open heart operations per million population were done followed by South America, Russia, Asia and Africa with 147 cases per million population, 37 cases per million population, 25 cases per million population and 18 cases per million population respectively. North America reported to have undertaken the maximum number of open heart surgeries and Africa reported to have performed the least number of open heart surgeries with an average of 169 cases of open heart surgeries per million population globally in accordance to the World Heart Federation (WHF) report in 2013, indicating the prevalence of patients undergoing cardiac surgeries.

In the year 2010, there were about 30,000 bypass surgeries done in the United Kingdom. Each year 694,000 open heart procedures were carried out which includes 104,000 valve replacement surgeries; 2,210 heart transplants and 4,48,000

CABG surgeries among which 323,000 were men and 1,25,000 were women. Indicating that CABG was the common cardiac surgery performed that to more common among males.

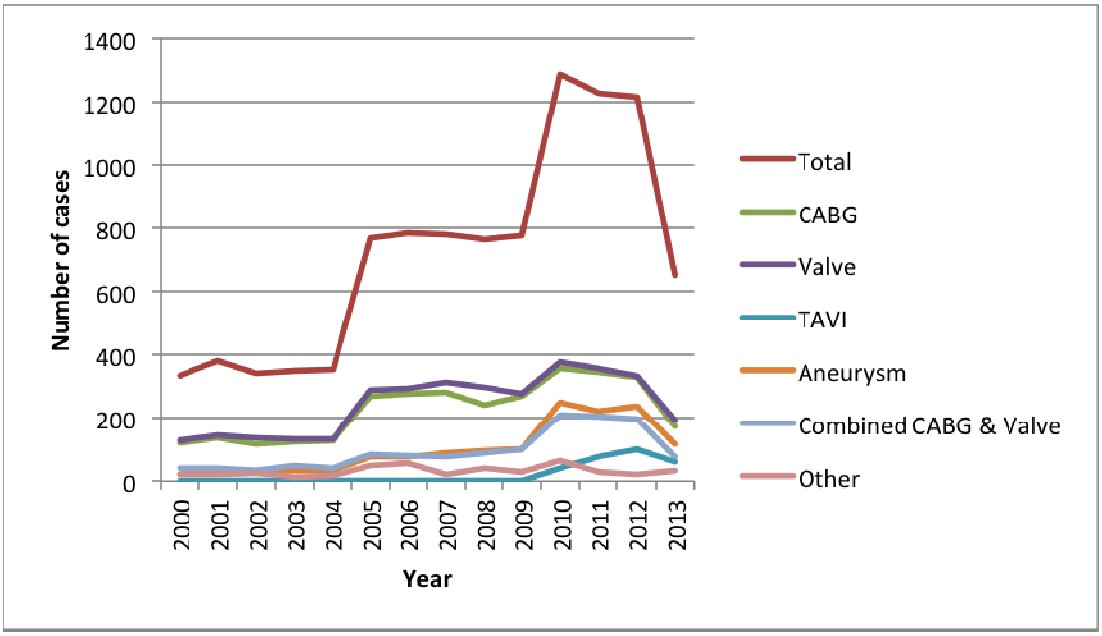

Fig.1.1.2: Total number of Cardio Vascular surgeries performed from the year 2000 to 2013 in United States of America.

Source: Annual report on Cardio Vascular surgeries in USA: WHO 2014

WHO (2014) states that among the total number of cardiovascular surgeries performed in United States of America (USA) a majority of them underwent valve replacement surgeries with an average of 200 thousand cases each year. This pattern continues to rise over the years with a total number of 375 thousand cases in the year 2013. This is followed by CABG, with a total number of cases drastically raised from 175 thousand cases in 200 to almost about 350 thousand cases in the year 2013. The total number of aneurysm repair surgeries and combined CABG and valve repair surgeries took the lead followed by CABG with 225 thousand cases and 200 thousand cases respectively in the year 2013.

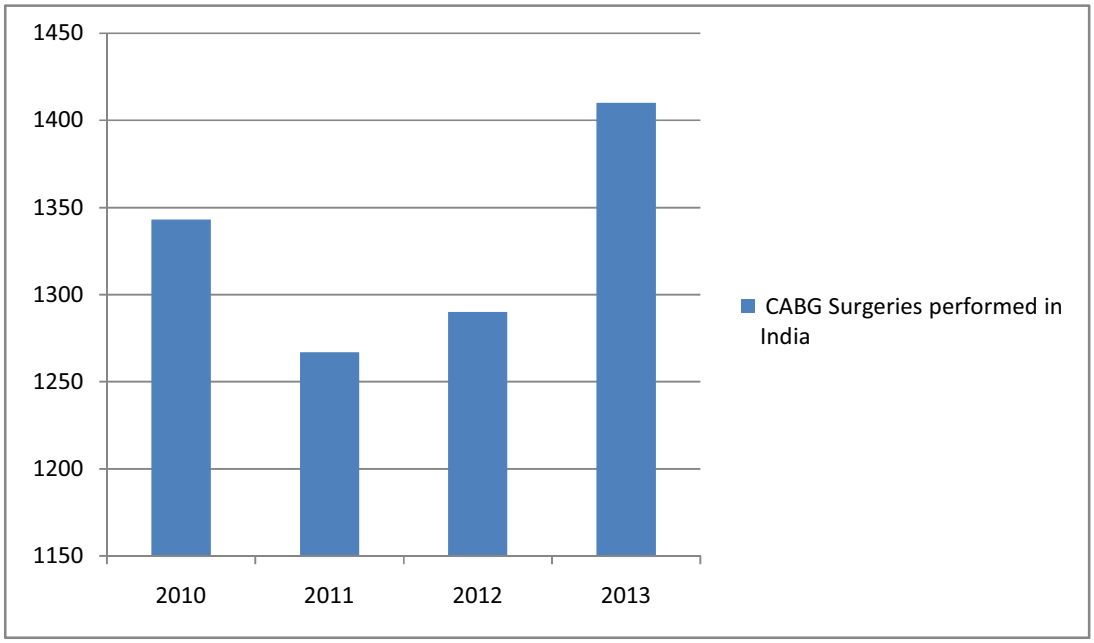

Fig.1.1.3: Total number of Coronary Artery Bypass Graft surgeries performed in India.

Source: Annual report on Cardio Vascular surgeries in India: Asian Heart Institute (AHI) 2014.

The AHI report (2014) affirms that the burden of cardiovascular diseases is increasing globally and India is becoming the capital of cardiovascular diseases. Cardiac surgery is on the rise, whether through disease, congenital defects or generalized degradation of cardiac function, over time cardiovascular diseases are increasing dramatically, substantiating the need for continued growth of cardiovascular surgery. Over the last 50 years India has made remarkable advances in the field of cardiac treatment. Cardiac surgery is on the rise globally. Over time the cardiovascular diseases are increasing vividly, substantiating the need for continued growth of cardiovascular surgery. According to the AHI report in 2014, about 50,000 - 60,000 cardio thoracic operations are performed every year in India, from 2000 - 2010. 1020 patients aged 65 underwent Isolated Aortic Valve Replacement, 820 patients underwent Minimally Invasive Direct Access Heart (MIDAHS) Valve Surgery and 252 patients underwent Mitral Valve Replacement (MVR).

With the rise in the number of cardiac surgeries globally, pain has also been reported as one of the primary sources of concern for cardiac surgery patients, and postoperative pain management is important owing to the increasing number of patients undergoing open heart surgery. Post operative pain for the cardiac surgery patients has many facets. Pain can be caused by incisions, intraoperative tissue retraction and dissection, multiple intravascular cannulations, chest tubes left after surgery, and multiple invasive procedures that patients undergo as part of their therapeutic regimen (Mueller et al., 2004). Puntillo (2000) in his study stated that the patients reported chest incision pain as a problem after Coronary Artery Bypass Graft (CABG) surgery. As a result of pain, patients cannot take deep breaths, cough, or start moving around as soon as they should, and this delays their recovery. Poorly controlled pain also contributes to hemodynamic instability, which can lead to myocardial ischemia (D'Arcy, 2002). Economic and medical implications, such as extended lengths of stay and patient dissatisfaction with medical care are associated with these complications (Apfelbaum et.al.2003). It is proposed that effective management of postoperative pain in patients who have undergone CABG surgery can be an important factor in overall recovery.

The assessment and management of acute post operative pain is an important aspect in the care of cardiac surgical patients. Evaluation is in fact the key to the treatment of pain. Without systematic assessment and evaluation, it becomes impossible to adequately and expertly treat pain. Pain is a subjective experience. As McCaffery (1986) emphasized, " Pain is whatever the experiencing person says it is, existing whenever he says it does". If someone perceives and expresses pain, then it must be considered to be a pain. Therefore the gold standard for pain assessment is a patient's self report (Barr et al., 2013). However the complexity and variety of pain responses in critically ill patients increases the difficulty of pain assessment. Hence owing to the subjective nature of things, assessment and management of pain can be a complex process. Evaluation of patient will include (1) evaluation of current vital signs, (2) evaluation of pain for its intensity, location and duration (3) evaluation of pain associated symptoms, (4) relieving and exacerbating factors related to pain (5) evaluation of side effects associated with treatment of pain.

Challenges such as lack of patient assessment and lack of appropriate use of analgesics have been reported (White & Kehlet, 2010). Timing, route and appropriate

use of analgesics need to be considered in the management of pain. Despite advances in pain management, such as patient controlled analgesia (PCA) and multimodal analgesia, patients continue to experience moderate to severe pain (Brown, Bedard, & Pruden, 2011).

Pain management is multifaceted and requires a multidisciplinary approach in improving patient outcomes. Pharmacological management should continue to be the cornerstone of the treatment of postoperative pain, however non pharmacologic methods of pain management are advantageous as they can enhance the effect of pain relieving medications. The nurse can make a significant contribution to pain control by being able to offer a variety of non pharmacological methods of pain relief that the patient may use in combination with the more traditional methods of analgesia or local anesthesia. Recent research supports some of the older methods of non pharmacological pain control such as distraction, especially humor; relaxation using the patient's own memory of peaceful events and cutaneous stimulation, especially use of cold. They are potentially useful for pain management in the ICU because they are low cost, easy to provide and safe. In addition, these techniques can help patients achieve a sense of control over pain (Van Kooten, 2001). But each person may respond to these therapies differently. However, they remain complementary to pharmacological treatment for pain relief.

In the early post operative period of the patients who have undergone cardiac surgeries, the presence of chest drains adds to the patients discomfort often resulting in severe deep visceral pain restricting the mobility of the patient. Drains are removed when drainage is minimal after cardiac surgery. Removal of chest drains is extremely painful and based on individual patient assessment an appropriate analgesic should be administered. Non Steroidal Anti Inflammatory Drugs (NSAIDs) have demonstrated opioid sparing effects in randomized trials after cardiac surgery. Meanwhile the cardiac surgeons and anesthesiologists have had safety concerns with NSAIDs regarding renal impairment and bleeding.

Hence a combination of pharmacological and non pharmacological methods of pain control yields the most effective pain relief for the patient. Non pharmacological interventions are useful and have the potential to further modulate nociceptor activity particularly in the dorsal horn of the spinal cord. Various interventions

include music therapy, reflexology, application of cold, ice pack, acupressure, back massage and so on. Application of cold has both systemic and local effects. Ice application slows the suppurative process and the absorption of tissue fluids, it restricts the movement of blood and the tissue fluids thus it relieves pain caused by increased amount of fluid moving into the tissues. It decreases the rate of tissue metabolism and thus decreases the demand upon the heart for food and oxygen. The use of cold application during and after a painful procedure such as chest tube removal decreases nerve conduction velocity and pain intensity and hence must be considered as a pain relieving measure.

The analgesic effects of application of cold can be explained by Melzack and Wall (1990) in "Gate control theory". According to the Gate control theory on meddling with the chest tube during its removal activates fibers within the parietal pleura, chest muscles and chest tube insertion site leading to the release of various excitatory neurotransmitters. Application of cold can also lead to the reduction or reversal of pain impulses by activating the descending inhibitory neurons by blocking the ascending nerve impulses which closes the "Gate" and the brain will not interpret the impulse as painful.

If pain is poorly managed it incurs the cost for both the individual and the society. The individual cost includes psychological distress, reduced function, development of chronic pain and reduced quality of life (Sommer, Van Kleef, & Marcus, 2012). Societal effects include inability to work and increased health care costs (Peters et al., 2010). Being free from pain is a patient's basic human right and under treatment of post opertative pain can aggravate patient outcomes. Patient comfort and pain management are also of major concern to patients and their families (Mularski, Heine, Osborne, Ganzini, & Curtis, 2012). Moreover pain has been promoted as the fifth vital sign for a decade, but there is little empirical evidence to suggest that doing so has affected the care of individuals suffering pain.

The role of the nurse is pivotal in the assessment and management of any pain and specifically post operative pain. Florence Nightingale, the pioneer in nursing set up an historic breakthrough in the profession through her simple yet remarkable steps accompanied with sound scientific body to ease the pain and suffering of the sick

wounded soldiers. Ever since the time of Nightingale, nurses have appreciated the important influence which environment had on patient response. Nurses by altering the environmental stimuli, they reduced the negative effect of pain by icing and compressing the cutaneous targets that transduces pain. Right from Nightingale's time meeting the psychosocial comfort needs of the patient was an important criteria in alleviating the pain. Pain assessment and reassessment are components in the nurse's role that serves as the key in pain management. Pain management is an integral part of nursing and we have the responsibility to effectively manage our patient's pain, but this does not always mean the use of an analgesic.

Effective pain management should be holistic in its approach. To provide optimal patient care, nurses require appropriate knowledge, skills and attitudes towards pain, pain assessment and its management. Nurses need to understand the pathophysiology of pain and recognize that pain management is vital in the recovery of postoperative patients. This must be based on the best available evidence to prevent patients from suffering harm **(Nursing Midwife Council, 2008).**

Research on pain has resulted in a better understanding of pain modalities and the development of new treatments. **The Department of Health and Human Services (2011)** testifies that the patients report an increase in satisfaction with the management of their pain during hospitalization. This examines how the deliberate use of ethical principles when making pain management decisions for hospitalized patients may provide more optimal outcomes.

1.2 SIGNIFICANCE OF THE STUDY

Pain is highly individualized. It is not the responsibility of the clients to prove they are in pain; it's the care givers responsibility to accept the client's report of pain according to **The American Pain Association (2009)**. The sensation of pain is different for each areas of the body and everyone responds to and experiences pain differently. Everyone responds to pain differently, as the difference in pain response can be due to factors like age, cultural or religious expectations, current emotional status, general medical status, pre-existing pain problems, prior experiences and expectations regarding pain. Individuals are born with varying thresholds of pain perception. Pain interferes with sleep, mobility, nutrition, thought, sexual activity, emotional well-being, creativity,

and self-actualization. Surprisingly, even though pain is such an important obstacle to comfort, it is one of the least understood, most undertreated by the healthcare providers. For this reason, some nurses add "comfort" to Maslow's hierarchy of basic human needs and further goes declaring the relief of pain as the "basic human right" in concurrence to the **American Pain Society (2009).**

The Chronic Pain Policy Coalition (2007) has acknowledged the management of pain as a high priority for nursing care as it is the fifth vital sign. **The Joint Commission for Accreditation of Health Care Organization Standards (JCAHO) (2008)** states that the relief of pain is a human right which includes expression of pain, appropriate assessment and management of pain**.**

The first step for effective pain management is pain assessment. However the pain of critically ill patients often is not correctly assessed (Payen et al., 2007). If pain is closely assessed in the way that vital signs are assessed such as heart rate, blood pressure, temperature and respiratory rate are; then it can be better and more intensively managed. For that reason it is important to have an effective pain assessment tools to avoid the risk of incorrect pain management. Most critical care nurses do not know how to effectively and objectively assess pain (Aslan, Badir, & Selimen, 2006). Nurses often distrust patients self-reporting of their pain, which suggests that they have their own benchmark of what is acceptable and when and how patients should express their pain. Documentation of pain by nurses has been shown to be poor, and even high pain scores do not result in nurses administering more analgesics (Watt-Watson et al, 2001). These tools to assess pain especially for critically ill patients are classified into two categories: Multidimensional pain assessment tool, which includes sensory, cognitive and affective dimensions of pain and Unidimensional pain scale which mainly focuses on patient self evaluated pain intensity. When patients are unable to report pain, behavioral observation and vital signs observation provides simple, fast, and objective method due to the availability of physiologic monitoring devices in Intensive Care Units (ICU). Several studies have demonstrated that heart rate (HR), blood pressure (BP) and respiration rate (RR) increases significantly when patients are in pain (Gelians & Johnston, 2008).

Cardiac surgery presents a life saving and life enhancing opportunity to hundreds of thousands of patients. Many patients face significant challenges during the post operative period including pain, anxiety and tension which can impair immune function and slow wound healing. During cardiac surgery chest tubes are inserted to ensure that fluid and air drains from the chest cavity to reduce severe cardiac and respiratory complications related to abnormal accumulation of air and fluids. Keeping chest tubes in place is associated with increased pain, discomfort, mechanical irritation of the heart and pericardium and increased risk of infection.

Chest drains are inserted in a wide range of situations, after cardiothoracic surgery, trauma, post operative complications and other medical conditions to drain pus, air or fluid from the lungs. These chest tubes are typically removed 24 -48 hrs after surgery or when the excess air, blood or fluid has been properly drained. Drains are usually removed when the drainage is minimal after cardiac surgery (<10 – 20 ml / hr). Removal of chest drains is extremely painful and based on individual patient assessment an appropriate analgesic should be administered (Parkin, 2002).

When the chest tube remains in place the endothelium that lines the chest cavity adheres to the tube, when the tube is removed, the pulling force may shear those adhesions and cause pain during removal which can be a painful and a frightening experience for the patients. Care should be taken to make the procedure occur with little pain and distress as possible. The removal of chest tubes has been described as one of the worst experiences in the Intensive Care Unit for the patients. Patients described chest tube removal as a painful event in the post operative recuperation and reported that the pain from the procedure was poorly managed.

Chest drain removal can be painful so analgesia and techniques to minimize pain should be used, for pain can be devastating and disruptive to the flow of life. Pain makes one feel unable to go to work, interact with friends and family, or to do their usual daily life activities. Pain can interfere with sleep and affect your mood as well. This loss of ability and independence can, in turn, affect ones sense of self-worth and self-esteem.

Fortunately, pain can be managed and even relieved through the right treatment. Today there are many options available to adequately control pain, and pain control is something you can aim. The non pharmacologic approach to pain management includes a wide variety of techniques that not only addresses the physical sensations of pain, but also prevent suffering by enhancing the psycho emotional and spiritual components of care. (Mc Cuffre, 2005). Heat-activated ion channels or receptors are thought to play a significant role in inflammation-related pain. They are effectively relieved by cooling by reducing the temperature to soft tissue by 10 to 15 degrees Celsius. By applying a cooling treatment it decreases local cell metabolism, reduces the oxygen requirement of the tissue and causes constriction of the peripheral blood vessels. Cooling treatments are applied intermittently in a number of ways, including solid or crushed ice applied directly or between layers of a pad or a gel pack application.

Studies examining the utilization of ice therapy in the ICU have also reported inconsistent findings over the last decade. In a study by Sauls, the application of either ice packets or tap water packets at the site of the chest tube for 10 minutes prior to removal led to significant decreases in cardiac surgery patient's pain scores post procedure. In a recent study by Demir and Khorshid, a 20-minute application of cold packs before chest tube removal was used. Pain intensity was significantly lower in postoperative ICU patients from the experimental group who had cold pack application and administration of an analgesic, compared with the control group who had only analgesic administered, during and 15 minutes after tube removal.

Parry M (2010) conducted a descriptive study to assess the pain experience of men and women after CABG. Participants included men(n=78) and women (n=17) who were having first time non emergency CABG surgery. The findings revealed that 47% of the women (n=8) had moderate to severe pain. It was statistically significant between groups with patients reporting moderate to severe pain with movement (p=.03) , walking (p=.01) and sleeping (p=.01).

Brooks J A (2004) conducted a descriptive study to assess the level of pain experienced after cardiac surgery among 10 post operative clients. The participants were asked to describe their pain levels for 5 activities expected of patients after cardiac

surgery on postoperative days 1 to 6 and changes in pain levels after chest tube removal and extubation. The findings revealed that Pain scores were higher on earlier postoperative days. The study concluded that Pain relief is an important outcome of care. A comprehensive individualized assessment of pain is necessary to promote satisfactory management of pain.

Jenny Sauls (2002) carried out a true experimental study to assess the effectiveness of ice as an intervention for pain intensity, pain distress and pain quality experience among 700 post cardiothoracic patients undergoing chest tube removal. The experimental group received ice; the control group received a placebo. The results of the findings revealed that pain intensity decreased in both groups after the ice and placebo intervention which suggests a placebo effect.

Mueller X M (2005) conducted a prospective study to analyse the duration of chest tube drainage on pain intensity and pain distribution among 80 patients after cardiac surgery. The findings revealed that there was less pain in short drainage group on post operative day 2(p=0.047) and less patients without pain on post operative day 3(p=0.01). The study results stated that a policy of early chest ablation limits pain sensation and simplifies nursing care without increasing the need for repeated pleural puncture.

Mohsen Mohammed (2010) conducted a prospective study to assess the impact of chest tube removal time following CABG among 307 patients who were randomly assigned to two groups at Isfahan University, Iran. In group 1 chest tubes were removed within 24 hours after surgery whereas in group 2 the chest tubes where removed in the second 24 hours after surgery. Respiratory rate and pain level were assessed. The findings revealed that the pain level evaluated 24 hours post-operation was lower in the first group, and the difference in the pain level between the 2 groups evaluated 30 hours post-operation was significant (P=0.016). The study concluded that early extracting of chest tubes after coronary artery bypass graft surgery when there is no significant drainage can lead to pain reduction and consuming oxygen which is an effective measure after surgery toward healing.

An exclusive administration of pharmacological agents prior to chest tube removal is the standard practice in most of the hospitals but still patients verbalizes pain and there were no other interventions in addition to reduce the intensity of pain of these patients on a general basis.

Cooling gel packs, considering its properties such as flexibility, reusable nature and its effectiveness in reducing pain caused by soft tissue injury was used in this study in combination with the routine hospital analgesics in reducing the pain associated with chest tube removal. Cooling gel packs were widely being used to reduce swelling and relieve pain caused by soft tissue injuries. These cooling gel packs were reusable in nature. They were flexible and it confined well to body parts especially around the chest tube as they were also available in horse shoe shape. The cooling gel pack was systematically proven to reduce pain and uphold the recovery caused due to soft tissue injury. A trial on cold gel packs were carried out for the first of its kind globally at the Kuopio University in collaboration with the university hospitals. This study using cooling gel pack was conducted by Dr. Olavi Airaksinen and the short report on the study had been published in the American Academy of physical medicine & rehabilitation. The trial showed that cooling gel packs were effective and its effect began instantly after its application and it reduced the pain perceived by almost half.

In the Madras Medical Mission hospital, daily about 5-8 patients undergo heart surgeries with chest tubes placed in their thoracic cavity. The researcher during her clinical posting and from her personal experience of working in ICU found out most of the patients expressing the agony of pain during chest tube removal in spite of the routine analgesics that had been administered. The researcher had confronted with several studies signifying the effectiveness of ice application in diminishing the pain associated with the chest tube removal among post operative patients. This has motivated the investigator to choose this topic for the study.

1.3 TITLE

"Effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai."

1.4 STATEMENT OF THE PROBLEM

A true experimental study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai.

1.5 OBJECTIVES OF THE STUDY

1. To assess the baseline and post test level of procedural pain in experimental and control group.
2. To assess the effectiveness of cryotherapy on the level of procedural pain between the experimental and control group.
3. To associate post test level of procedural pain with selected demographic and clinical variables of experimental group.

1.6 OPERATIONAL DEFINITION

1.6.1 Effectiveness

It refers to the changes in the level of pain during the chest tube removal (CTR) among the cardiac post operative patients after receiving cryotherapy along with the administration of hospital routine (Inj. Perfalgan) 30 minutes prior to the chest tube removal. Pain was assessed using visual analogue scale (VAS) and modified comfort Scale which included observation of physical and physiological parameters like heart rate, blood pressure, respiratory rate and Spo_2.

1.6.2 Cryotherapy

It refers to the application of cooling gel packs which were wrapped with sterile gauze and kept around chest tube site for fifteen minutes, prior to the chest tube removal.

1.6.3 Procedural pain

It refers to the pain (intensity and distress) resulting from the removal of chest tube from the thoracic cavity which was assessed using visual analogue scale and modified comfort scale for the patients who had undergone cardiac surgeries.

1.6.4 Cardiac post-operative patients

It refers to the patients who had undergone cardiac surgeries such as Coronary artery bypass graft- on pump or off pump- coronary artery bypass or valve replacement or valve repair surgery with chest tube in the thoracic cavity.

1.7 NULL HYPOTHESES

NH_1 : There is no significant difference in the post test level of procedural pain among the cardiac post operative patients between the experimental and control group at $p<0.05$.

NH_2 : There is no significant association of the level of procedural pain with selected demographic and clinical variables of the experimental group at $p<0.05$.

1.8 ASSUMPTION

1. Chest tube removal causes severe agonizing pain for the patient's inspite of the routine analgesics being administered.
2. The patients undergoing chest tube removal need additional therapies to manage their pain along with the routine analgesics.
3. Ice application has an effect in reducing any pain.

1.9 DELIMITATION

The study was delimited to

1) A period of 4 weeks of data collection.
2) Cardiac post operative patients with chest tube only
3) Cardiac post operative patients in Madras Medical Mission (MMM) hospital.

1.10 CONCEPTUAL FRAMEWORK

1.10.1 GENERAL CONCEPTS OF WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY:

According to Wiedenbach, nursing is nurturing and caring for someone in a motherly fashion. Nursing is a helping service that is rendered with compassion, strong understanding for those in need of care, counsel and confidence in the area of health.

Perspective theory directs action towards an explicit goal and it consists of three factors

1) Central purpose
2) Prescription
3) Realities in immediate situation

The nurse develops prescription based on the central purpose and implements in accordance to the realities of the situation.

1) **Central purpose:** The quality of health nurse desires to sustain in her patient and specifies what she recognizes to be her special responsibilities in caring for the patient.
2) **Prescription:** Nature of action that will most likely lead to fulfillment of nurse's central purpose.
3) **Realities:** Factors influencing the fulfillment of central purposes**.** Wiedenbach defines five realities namely

a) Agent: Is a practicing nurse who engages in innumerable acts.

b) Recipient: Patient who has personal attributes problems, capabilities, aspiration and abilities to cope.

c) Goal: Desired outcome nurse wishes to achieve for her patient.

d) Means: Activities and devices through which practitioner is enabled to attend her goal.

e) Framework: context with in which nursing goal is practiced.

According to Wiedenbach, nursing practice consists of:

1. Identifying the patients need for help
2. Ministering the needed help
3. Validating that the need for help was met

1. Identifying the patients need for help:

Identification involves viewing the patient as an individual with unique experiences and understanding the patient's perception of the condition. The nurse determines the patients need for help based on the existence of the need, whether the patient realizes the need, what prevents the patient from meeting the need and whether patient can meet the need alone.

2. Ministering the needed help:

Ministration refers to provision of needed help. The nurse formulates a plan for meeting the patients need for help based on the available resources. What the patient thinks, knows, can do and has done plus what the nurse thinks, knows, can do and has done. The nurse presents the plan to the patient and the patient responds to it.

3. Validating that the need for help was met:

Validation refers to a collection of evidence that shows the patient needs has been meet and his functional ability has been restored as a direct result of nurses action.

1.10.2 APPLICATION OF MODIFIED WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY FOR THE PRESENT STUDY:

Perspective theory for nursing is described as concerning a desired situation and ways to attain it. Theory directs action towards an explicit goal.

Nursing practice consists of:

1) **Identifying the patients need for help**
2) **Ministering the needed help**
3) **Validating that the need for help was met**

1) Identifying the patients need for help:

a) **Observation of patient:** In the identification component nurses observes the patient looking for inconsistency and attempts to clarify the inconsistency and finally identifies the needed help. Hence the nurse / researcher by assessing the demographic characteristics, clinical variables and baseline pain distress and intensity of pain, identifies that the patient is suffering or experiencing the pain.

b) **Central purpose:** The nurse desires that the patient should be free of pain or should have tolerable level of pain.

c) **Prescription:** Practitioner directed action to achieve the central purpose; the nurse decides to prescribe the application of cooling gel pack.

2) Ministering the needed help:

Here the nurse implements the practitioner directed interventions by application of cryotherapy (15 minutes) around the chest tube along with the hospital routine (Inj.Perfelgan-30 minutes) prior to CTR for the experimental group under the existing realities. Realities in the study refer to the control group which only receives hospital routine.

3) Validating that the need for help was met:

Here the nurse validates whether the cryotherapy was indeed helpful in reducing procedural pain. The nurse obtains information from the patient whether the purpose of the nursing action has been fulfilled or not by means of post assessment I and post assessment II. Here she makes use of the VAS (pain intensity) and comfort scale (pain distress). Post test I within 5 minutes from CTR and post test II within 20 minutes from CTR.

Nursing is a practice of identifying a patient's need for help through observation of presenting behaviors and symptoms, exploration of the meaning of those symptoms with the patient, determining the cause(s) of discomfort and determining the patient's ability to resolve the discomfort or if the patient has a need for help from the nurse or other healthcare professionals. Thus by adopting the modified Wiedenbach's helping art theory the nurse researcher was able to bring out the changes in the level of procedural pain (pain intensity and pain distress) perceived by the cardiac post operative patients .

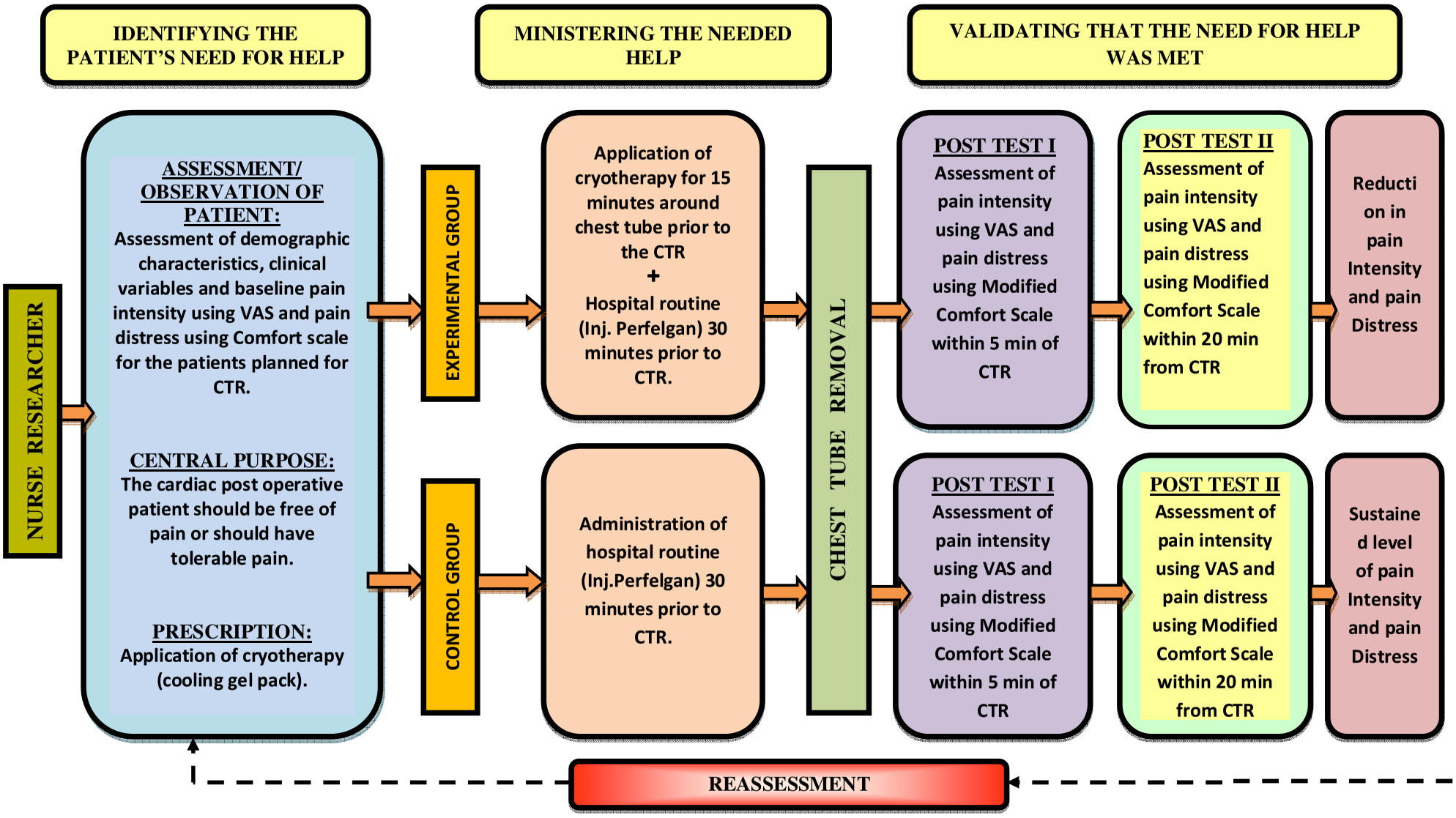

Fig.1.10.1: Conceptual framework based on Modified Wiedenbach's Helping Art Theory

REVIEW OF LITERATURE

CHAPTER – 2

REVIEW OF LITERATURE

Review of literature is a systematic search of published work to gain information about a research topic. Through the literature review, researcher generates a view about what is known about a particular situation and lays a foundation for the research plan. It provides a background for the current knowledge on the topic and illuminates the significance of the study. The present literature review was based on extensive surveys of journals, books and International nursing studies, a review of literature relevant to the study was undertaken which helped the investigator to develop deep insight into the problem.

The logical sequence of the chapter is organized in the following sections:

2.1: General concepts of chest tube removal

2.2: Research reviews

2.2.1 Section A: Reviews related to pain after cardio thoracic surgeries and chest tube drainage.

2.2.2 Section B: Reviews related to effectiveness of cold application on pain reduction.

2.2.3 Section C: Reviews related to various measures to control pain on chest tube removal.

2.2.4 Section D: Reviews related to effectiveness of cooling gel pack in reduction of pain during chest tube removal.

2.1: General concepts of Chest Tube Removal

Introduction

Chest tube also called as chest drains are inserted to allow drainage of blood, air or fluid from pleura, allowing expansion of the lungs and restoration of negative pressure in the thoracic cavity. It is indicated for post operative patients e.g. cardiac surgery, thoracotomy and for some medical conditions such as pneumothorax, haemothorax, chylothorax and in case of pleural effusions. Chest tubes are routinely placed in theatre, intensive care units, or in emergency department and ward areas in emergency situations.

Indications for Chest Tube Removal

1. Absence of an air leak (pneumothorax)
2. Drainage diminishes to little or nothing
3. No evidence of respiratory compromise
4. Chest X ray showing lung re-expansion

Patient preparation for CTR

1. Ensure patient is fastened, has adequate pain control, sedation and distraction therapy given.
2. Consider the environment i.e. treating room, privacy screens.
3. Heparin infusions for cardiac patients should not be discontinued prior to drain removal.

Post procedural patient care for CTR

1. Attend to patients comfort and sedation score as per the guidelines.
2. Chest X Ray (CXR) should be done post drain removal.
3. Clinical status is the best indicator for reaccumulation of air or fluid.
4. Monitor vital signs closely (HR, RR, BP and SpO2) on removal and then every hour for 4 hours post removal.
5. Document the removal of drain in progress notes and on patient care record.
6. Remove the sutures 5 days of post drain removal.

Complications of CTR

1. Pneumothorax
2. Bleeding
3. Infection: erythema, fever, purulent discharge.

2.2: Research reviews

2.2.1 Section A: Reviews related to pain after cardio thoracic surgeries and chest tube drainage.

Miranda Ade F (2011) carried out a descriptive explorative study to evaluate the pain intensity and vital signs after cardiac surgery among 38 patients during their postoperative period. The findings of the data which were measured before and after performing the nursing procedure indicated that the manifestation of pain occurred at

different levels and the main changes in vital signs were referred to blood pressure. The study concluded that there was a significant relationship between the pain intensity and the vital signs.

Arbour C Gelinas (2010) conducted a descriptive study to evaluate the effectiveness of vital signs as a valid indicator for the assessment of pain among 105 postoperative cardiac ICU clients who were observed during three periods namely (1) unconscious and mechanically ventilated, (2) conscious and mechanically ventilated and (3) after extubation at a cardiology health center in Canada. During these testing periods, vital signs were assessed using the ICU monitoring at rest, during a nociceptive procedure and 20 min post-procedure. The findings revealed significant changes in most vital signs. The study concluded that vital signs should only be used as a cue when behavioral indicators were no longer available in mechanically ventilated or unconscious patients.

Aslan F et al (2010) evaluated the pain perception after cardiac surgery among 300 adult patients who stayed in cardiac surgical ICU post-operatively for a minimum of 48 hours who had sternal incision, chest tube and mechanical ventilator. The data was collected using face-to-face interview by the researchers following transfer from ICU to the surgical ward within 48 hours. The findings revealed that most patients described their pain as aching (n = 177) and throbbing (n = 154). The presence of chest tubes (n = 95), endotracheal tube suctioning (n = 47), change of dressings (n = 27) and the use of air mattresses (n = 20) were identified as painful experiences. The study concluded that cardiac surgery patients verbalized their pain experience with different words and identified different situations that decreased or increased their pain, which showed the subjective and complex nature of pain. A majority of them reported presence of chest tube as most painful event.

Cutshall S M (2010) conducted a true experimental study to assess the level of pain, anxiety, tension and satisfaction scores among 58 cardiac surgical patients before and after massage therapy for 20 minutes at St Mary's hospital, Minneosta. The findings revealed that there was a statistically and clinically significant decrease in pain, anxiety and tension scores among the study group. Thus the massage therapy may be considered important therapy for inclusion in the management of post operative recovery of cardio vascular surgical patients.

Mohsen Mohammed (2010) conducted a prospective study to assess the impact of chest tube indwell time following CABG among 307 patients who were randomly assigned to two groups at Isfahan University, Iran. In group one chest tubes were removed within 24 hours after surgery whereas in group two the chest tubes where removed in the second 24 hours after surgery. Respiratory rate and pain levels were assessed. The findings revealed that the pain level evaluated at 24 hours posoperatively was lower in the first group and the difference in the pain level between the second group evaluated at 30 hours postoperatively was significant (P=0.016). The study concluded that early extracting of chest tubes after coronary artery bypass graft surgery when there is no significant drainage can lead to pain reduction and consuming oxygen which is an effective measure after surgery towards healing.

Parry M (2010) carried out a descriptive study to assess the pain experience of men and women after CABG. Participants included male patients (n=78) and female patients (n=17) who were having first time non emergency CABG surgery. The findings revealed that 47% of the women (n=8) had moderate to severe pain. It was statistically significant between groups reporting to have moderate to severe pain with movement (p=.03) , walking (p=.01) and sleeping (p=.01).

Van Gullick (2010) explored the effectiveness of a pain management programme by conducting a prospective two phase study. All staffs were trained in assessing pain and to assess the pain scores three times a day and the preferred analgesic treatment was optimized among 190 post operative cardiac patients in the ICU. The findings revealed that patients in the intervention group were with a higher Numeric rating scale scores received higher morphine amounts. In control group no such relationship was observed. The study concluded that the intervention programme successfully reduced the occurrence of unacceptable level of pain and recommended that pain management should focus on the prevention of pain.

Baumgarten M C (2009) had done a cross sectional study to assess the lung function among 70 patients undergoing heart surgery using incentive spirometry. The findings revealed that the pulmonary function was significantly impaired in the post operative compared to the pre operative period ($p<0.01$). The study concluded

that the pulmonary function showed a significant relationship with pain and hence pain needs to be managed well postoperatively.

Diby M (2008) evaluated the effectiveness of post operative pain treatment program in reducing pain among 133 patients undergoing cardio thoracic surgery by conducting a prospective quasi experimental study which comprises of three periods and implementation of the algorithm for acute pain management and reassessment. The effectiveness was assessed using visual analog scales (VAS) for pain, morphine consumption, pain perception and sleep quality during their stay in the surgical ICU and after 1 month and 6 months. The findings revealed that the proportion of patients with no pain or often without pain increased from 11% to 37% (P = .005). The number of patients with sleep disturbances decreased from 68% to 35% (P = .012). No differences were observed at 1 and 6 months postoperatively. The study concluded that after algorithm implementation in the SICU, pain intensity at rest decreased and the quality of sleep improved for the patients.

Gelinas (2007) conducted a descriptive study about the pain experience among 93 patients who underwent cardiac surgery using a questionnaire about their pain experience during their stay in the ICU. Sixty-one patients (65.6%) recalled being ventilated and 72 patients (77.4%) recalled having pain, the patients (47.3%) identified the thorax as the location of their pain. Pain was mild for 16 patients, moderate for 21 and severe for 25 of them. The study concluded that evidence from research about clinical guidelines for pain management needs to be applied to the care of cardiac surgery patients in order to reduce patient suffering.

Sendelbach (2006) conducted an experimental study to assess the effectiveness of music therapy on physiological and psychological outcomes among 86 patients who underwent cardiac surgery, 50 in the experimental and 36 in the control group. The findings revealed a significant reduction in anxiety ($p<0.01$), pain ($p<0.01$), systolic BP ($p<0.001$) and heart rate ($p<0.001$). The study concluded stating that patients recovering from cardiac surgery may benefit from music therapy.

Francine Tinguely (2005) carried out a prospective study to assess the pain location, distribution and intensity of pain among 200 adult cardiac surgery patients

during their post operative hospital stay at a cardiovascular clinic, Switzerland using numeric pain rating scale. The findings revealed that the maximal pain intensity was significantly higher on the post operative day one and lower on the postoperative days three and seven. The study results demonstrated that the post operative pain has many facets and pain can be caused by incisions, intraoperative tissue retraction, dissection, multiple intra vascular cannulation and chest tubes left after surgery. Among which chest tube removal was reported to be most painful.

Mueller X M (2005) had done a prospective study to analyze the duration of chest tube drainage on pain intensity and pain distribution among 80 patients after cardiac surgery. The findings revealed that there was less pain in short drainage group on post operative day two (p=0.047) and less patients without pain on post operative day three (p=0.01). The study results stated that a policy of early chest ablation limits pain sensation and simplifies nursing care without increasing the need for repeated pleural puncture.

Brooks J A (2004) conducted a descriptive study to assess the level of pain experienced after cardiac surgery among 10 postoperative clients. The participants were asked to describe their pain levels for five activities expected of patients after cardiac surgery on postoperative days one to six and the changes in pain levels after chest tube removal and extubation. The findings revealed that the pain scores were higher on earlier postoperative days. The study concluded that pain relief is an important outcome of care. A comprehensive individualized assessment of pain is necessary to promote satisfactory management of pain.

Roshkovs (2004) conducted a descriptive study to assess the patients pain perception during epicardial pacing wire (EPW) removal among 100 CABG patients using McGill pain questionnaire. The findings revealed that the pain intensity was reported as mild (47%), while the main sensation experienced was pulling (70%). Age, gender, previous cardiac surgery and use of analgesics did not influence the pain and sensations experienced. The study concluded that CABG patients can be prepared for EPW removal by providing information that the procedure is mildly painful.

Jensen L (2004) carried out a descriptive study to describe the level of pain among 30 patients undergoing post surgical repair for congenital heart defects, using the McGill short form questionnaire (MSFQ), a visual analogue pain scale (VAP) and recordings of other variables (analgesic, anxiety, activity level) three times daily until hospital discharge. The findings revealed that mean pain intensity scores ranged from 2.44 +/- 1.31 following extubation to 1.30 +/- 0.66 on post-operative day (POD) five. The study concluded that no relationships were found among pain and other demographic, treatment, or clinical variables and pain was reported as mild to moderate intensity, variable in sensations, decreased over time and adequately managed.

2.2.2 Section B: Reviews related to effectiveness of cold application on pain reduction.

Li fang et al (2011) carried out a quasi experimental study to assess whether cryotherpay had an effect on reducing the pain associated with arthroscopy among 59 patients. They patients were assigned to the experimental group (n=33) and control group (n=26). In the experimental group ice was applied for 10 minutes with 50-minute interval for three consecutive sessions. The study exposed that the pain score among the experimental group reduced from 5·12 to 1·82 after cryotherapy, while the pain score among the patients in the control group decreased from 4·04–2·88. The findings of the study revealed that ice in a plastic bag can be applied as a regular practice for patients who have undergone arthroscopic surgery.

Yava et al (2011) assessed the effect of local cold application in reducing the incidence, severity and pain/sensitivity of skin burns in patients who underwent Trans Thoracic cardioversion (TTC) by carrying out an experimental study among 48 patients. The patients were assigned to study (n=24) and control groups (n=24). Local cold application was performed for a 14 hours period on patients in the study group, whereas only clinical procedures were applied in the control group following TTC. The findings of the study revealed that the incidence of burn and Pain/sensitivity scores was significantly lower in the study group ($p<0.05$). The results suggested that local cold application following TTC is an effective means of reducing the incidence and severity of burns and pain sensitivity.

Chailler M et al (2010) evaluated the effectiveness of cold therapy for the management of pain associated with deep breathing and coughing by carrying out a prospective study among 32 post operative cardiac surgical patients. Pain scores from 0 to 10 at rest were compared with pain scores during deep breathing and coughing with and without the ice gel pack. The findings revealed that repeated measures analysis of variance revealed a significant reduction in pain scores between pre- and post-application of the gel pack ($F = 28.69$, $p < .001$). There were 22 (69%) participants who preferred the application of the gel pack compared with no gel pack. The study outcome showed that cold therapy can be used to manage sternal incision pain during deep breathing and coughing.

Saeliw et al (2010) conducted a prospective randomised single blinded study to assess the effectiveness of ice application on patients comfort before and after botulinum toxin type A injections among 60 patients who underwent botulinum toxin A treatment. Participants were divided into three groups, group one where ice was applied for five minutes before the injection, in group two ice was applied 5 minutes after the injection and group three served as a control, receiving injections without ice application. A numeric pain distress scale was used to assess the pain intensity. The ratings indicated that pain was significantly reduced in group 1 compared to group 3 ($p = 0.005$), but there was not a significant difference between groups 1 and 2 ($p = 0.109$) or between groups 2 and 3 ($p = 0.448$). The study concluded that using an ice application 5 minutes before or after injection showed no difference but both significantly reduced pain compared to those without ice application.

Koc M et al (2006) conducted a prospective randomised study to assess the effectiveness of cryotherapy in reduction of post-operative pain following hernia surgery among forty post operative patients. Postoperatively the intervention consisted of chipped ice in a plastic bag and a plastic bag containing only room temperature water (control) were placed over the incision for 20 minutes. Postoperative pain data were collected at 2nd, 6th and 24th hour after operation using visual analogue scale (VAS). The highest pain levels were recorded 2 hours postoperatively for both groups. There was significant difference in the VAS scores between the groups at 2nd, 6th and 24th hour. The study findings suggested that local cooling is a safe and effective technique for providing analgesia following inguinal hernia repair.

George K P et al (2004) conducted an experimental study to assess the effectiveness of cryotherapy on nerve conduction velocity (NCV), pain threshold (PTH) and pain tolerance (PTO) among adult male sports players (n=23). The outcome measures were assessed at two sites served by the tibial nerve: one receiving cryotherapy and one not receiving cryotherapy. The findings of the study revealed that Cryotherapy lead to an increased PTH and PTO at both assessment sites ($p<0.05$). The study concluded stating that cryotherapy can increase PTH and PTO at the ankle and this was associated with a significant decrease in NCV. Reduced NCV at the ankle may be a mechanism by which cryotherapy achieves its clinical goals.

2.2.3 Section C: Reviews related to various measures to control pain on chest tube removal.

Friesner S A (2006) undertook a quasi experimental study to evaluate the efficiency of two pain-management approach during Chest Tube Removal (CTR) in 40 adults who had undergone coronary artery bypass graft surgery. The pain management approaches used were relaxation exercise with opioids and opioids alone. The pain was assessed using a 10-cm vertical Visual Analogue Scale to measure pain at three points, before CTR, immediately after CTR, and 15 minutes after CTR. The findings revealed a significant difference in pain ratings immediately after CTR and 15 minutes after CTR for the group receiving relaxation exercise as an adjunct to opioid analgesics. This study supported the use of a slow deep-breathing relaxation exercise as an adjunct to the use of opioids for pain management during CTR among cardiac surgery.

Broscious S K et al (2004) conducted an experimental study to assess the effect of music on pain among 156 cardiac postoperative patients. They were assigned into two groups, control group received music therapy alone and the experimental group received both music and hospital routine during chest tube removal after cardiac surgery. The pain was rated once after chest tube removal and 15 minutes later using the Numeric pain rating scale and physiological variables. The findings exposed that self-reported pain intensity, physiological responses and narcotic intake of the patient after chest tube removal had no much difference on the level of pain perceived by both groups. The findings revealed that a majority of the patients enjoyed listening to the music, and therefore music could be used as an adjuvant to other therapies.

Puntillo J et al (**2004**) did an experimental study to assess various pharmacological interventions in order to lighten the pain associated with chest tube removal among cardiac operative patients. A randomized study was done using four analgesics as intervention among 74 patients. The study findings revealed that pain intensity; pain distress and sedation levels had no significant difference between the two groups. Procedural pain intensity and pain distress scores for all were also found to be low. Patients were alert, no matter of which analgesic was administered. The study drew an inference and concluded that if either an opioid (morphine) or a non steroidal anti-inflammatory (ketorolac) correctly used this would significantly reduce the pain associated with chest tube removal without causing any undesirable sedative effects.

Houston S (2002) examined the effectiveness of quick relaxation technique (QRT) on pain associated with chest tube removal by conducting an experimental study among 24 patients who had undergone primary aorta-coronary bypass surgery at St. Lords hospital, Texas by using visual analogue scale immediately following CTR and 30 minutes later. Results indicated that those who received QRT in conjunction with analgesics reported less than half the amount of pain experienced by those who did not receive QRT. The study suggested that for most patients, the combination of analgesics and relaxation exercises is more effective in decreasing pain during CTR than when analgesics are administered without relaxation exercises.

2.2.4 Section D: Reviews related to effectiveness of cooling gel pack in reduction of pain during chest tube removal.

Yi-Rong Chen et al (2015) explored on the effectiveness of a cold application for pain associated with chest tube removal. This review focused on studies published before June 2014 that were indexed in the following databases namely; Cochrane Library, pubmed, MEDLINE, CINAHL and National Digital Library of theses and dissertations in Taiwan. Randomized controlled trials that evaluated the efficacy of cold application in patients before CTR were included in analysis. Study quality was assessed using the Modified Jadad scale and out of 426 participants the researchers terminated the cold application when patients' skin temperature reached 13℃ or after 20 minutes showed that the cold application immediately reduced the pain associated with CTR. It was also observed that the cold application prolonged the duration of time between the CTR and the administration of analgesics. Two studies in which analgesics were

administered to participants 60 minutes before CTR showed that cold application in combination with analgesics administration reduced patient pain due to the enhancement affects of CTR, which obtained results that were better than analgesics administration alone.

Heidari Gorji et al (2014) explored the effects of cold therapy and relaxation on pain of CTR among the patients who had undergone coronary artery bypass graft surgery by conducting a clinical trial on 80 post-cardiac surgery patients in the heart hospital of Sari-Iran. The patients were assigned to three randomized groups that included cold therapy, relaxation, and control groups. The groups had no significant differences in pain intensity before CTR, but immediately after CTR there was a significant difference between the treatment group (cold application and relaxation groups) and control group. There was no significant difference between relaxation and cold therapy groups. Both the relaxation and cold application methods showed relatively equal effects on reducing the pain owing to CTR.

Mitra Payami et al (2014) carried out a study on the effect of cold application in combination with Indomethacin suppository on chest tube removal pain in patients undergoing open heart surgery. A single-blind, double-group clinical trial was carried out on 146 patients who underwent open heart surgery during the study period, 68 patients were selected using convenience sampling method. The participants were randomly allocated to the intervention and placebo groups. Visual pain scale (VAS) was used to measure the perceived pain intensity. The mean pain intensity scores before, immediately and 15 min after the CTR were compared in both placebo and intervention and the results indicated that there was an immediate decrease in the pain intensity in the intervention group than the control group after the CTR.

Nurcan Ertug (2011) evaluated the effect of cold application on pain due to chest tube removal by carrying out an experimental study among 140 patients at Thoracic hospital, Turkey. The study group received cold application prior to chest tube removal and pain intensity was assessed in both groups using visual analogue scale. The findings showed that there was a significant difference in pain between the two groups. The results confirmed that cold application was effective in reducing the pain due to chest tube removal.

Emine Kol et al (2010) conducted a randomised study to evaluate the effectiveness of ice for the control of pain associated with chest tube irritation among 40 patients who underwent thoracotomy with chest tube placement using verbal category scale and behavioural pain scale methods. The findings revealed that the average pain severity scores were found to be significantly lower in the study group patients who received cold therapy when compared with the control group. The use of analgesic was not as much in the study group than in that of the control group. The study concluded that, in the study group the use of analgesics was less on comparing with the control group.

Yurdanur Demir et al (2010) conducted an experimental study to assess the effectiveness of cold application in combination with standard analgesic administration on pain and anxiety during chest tube removal among 90 patients with Body Mass Index less than 30. They were divided into 2 groups, one group with cold application and standard analgesics while the other group where standard analgesics alone was administered. The intensity of pain was measured using visual analogue scale. The findings revealed that the reduction in pain intensity associated with chest tube removal on application of cold was found to be statistically significant with a moderate level of pain. The study findings revealed that application of cold packs would reduced the intensity of pain during CTR but had no effect on reducing the anxiety levels or pain quality associated with CTR. The study suggested that cold application can be used for pain management during chest tube removal.

Jenny Sauls (2002) assessed the effectiveness of ice as an intervention for pain intensity, pain distress and pain quality experience by conducting a true experimental study among 700 post cardiothoracic patients undergoing chest tube removal. The experimental group received ice; the control group received a placebo. The results of the findings revealed that pain intensity decreased in both groups after the ice and placebo intervention which suggests a placebo effect. The study suggested that using a longer period of ice application with a larger sample size and replication of the study using 3 groups one with ice, one with placebo and one with only customary treatment may yield significant results.

METHODOLOGY

CHAPTER – 3

RESEARCH METHODOLOGY

This chapter deals with the methodology adopted for the study. It includes the research design, variables, setting, population, sample and criteria for selection of the sample, sample size, sampling technique, development and description of the tool, content validity, pilot study, and reliability of the tool, data collection procedure and plan for data analysis.

3.1 RESEARCH APPROACH

A research approach is an applied form of research that involves finding out how a specific program, practice, procedure or policy is working well **(Polit & Hungler).**

Quantitative research approach was adopted for this study to accomplish the objectives of the study.

3.2 RESEARCH DESIGN

It refers to the overall plan for obtaining answer in the research questions for testing the research hypothesis **(Polit & Hungler).**

The effectiveness of cryotherapy can be proved only if there was a comparison; hence the researcher needed to assess the effectiveness of cryotherapy on the procedural pain among the cardiac post operative patients between the experimental and control group giving an equal opportunity for thee cardiac post operative patients through random sampling. The research design used for this study was true experimental post test only design comprising of randomization, manipulation and control in order to validate the outcome of this study.

	GROUP	BASELINE ASSESSMENT (30 minutes before CTR)	INTERVENTION ×		POST TEST I O_1 (Within 5 minutes from CTR)	POST TEST II O_2 (20 minutes from CTR)
RANDOMIZATION	Experimental group N=40	Pain was assessed using VAS and Modified Comfort Scale including observation of physical and physiological parameters for the patients planned for CTR.	Application of cryotherapy for 15 minutes around chest tube, prior to the CTR + Hospital routine (Inj. Perfelgan) 30 minutes prior to CTR.	CHEST TUBE REMOVAL	Level of procedural pain was assessed using VAS and Modified Comfort Scale including observation of physical and physiological parameters.	Assessed level of procedural pain using VAS and Modified Comfort Scale including observation of physical and physiological parameters
	Control group N=40	Pain was assessed using VAS and Modified Comfort Scale including observation of physical and physiological parameters for the patients planned for CTR.	Application of hospital routine (Inj. Perfalgan) 30 minutes prior to CTR.		Level of procedural pain was assessed using VAS and Modified Comfort Scale including observation of physical and physiological parameters.	Assessed level of procedural pain using VAS and Modified Comfort Scale including observation of physical and physiological parameters.

3.3 VARIABLES

3.3.1 Independent Variable

The independent variable of the study was Cryotherapy.

3.3.2 Dependent Variable

The dependent variable of the study was level of procedural pain.

3.3.3 Background Variables

Demographic variables consisted of parameters such as age, gender, educational qualification and occupation.

Clinical variables consisted of parameters such as Body Mass Index, history of previous surgeries, nature of cardiac surgery undergone, total number of chest tubes, size of chest tube and indwell time of chest tube.

3.4 RESEARCH SETTING

The study was conducted at Madras Medical Mission Hospital, Chennai. It is a 281 bedded multi speciality hospital. With regard to cardiology department it has a 225 bedded cardiothoracic unit which consists of Cath lab, cardiac OT, Adult ICU, step-down ICU and cardiac wards. Approximately, on an average about 125 open heart surgeries are performed every month. The researcher conducted the study at adult ICU which was 25 bedded postoperative ICU receiving patients immediately after the surgery from cardiac Operation theatre.

3.5 POPULATION

Population is the entire aggregation of clients with similar characteristics and on whom the researcher would generalize the study findings. The population encompasses the target population and accessible population.

3.5.1 Target population

All the cardiac post operative patients who had undergone cardiac surgeries like coronary artery bypass graft- on pump, off pump coronary artery bypass or valve replacement or valve repair surgery with chest tube in the thoracic cavity at the hospitals in Tamil Nadu.

3.5.2 Accessible population

All the cardiac post operative patients who had undergone cardiac surgeries like coronary artery bypass graft- on pump, off pump coronary artery bypass or valve replacement or valve repair surgery with chest tube in the thoracic cavity at Madras Medical Mission hospital.

3.6 SAMPLE

All cardiac postoperative patients, who had undergone cardiac surgeries like coronary artery bypass graft- on pump, off pump coronary artery bypass or valve

replacement or valve repair surgery with chest tube in the thoracic cavity at Madras Medical Mission hospital, who fulfilled the sample selection criteria.

3.7 SAMPLE SIZE

The sample size was estimated by power analysis. The total sample consisted of 80 cardiac post operative patients (40 in experimental group and 40 in control group) who were transferred to Adult ICU from cardiac OT after surgery and who fulfilled the sample selection criteria.

3.8 SAMPLING TECHNIQUE

Sampling technique refers to the process of selecting a group of people, events and other elements that are representative of the population being studied **(Polit & Hungler).**

At first the surgery list, of all cardiac patients posted for the surgery was collected on daily basis from the cardiac operation theatre by the researcher. Then as the patients were received at AICU from the cardiac OT the samples that fulfilled the selection criteria were selected by simple random sampling technique using lottery method. The investigator allocated the samples on the basis of lots, those with lot **"E"** was assigned to the experimental group and those with lot **"C"** was assigned to the control group. Similarly the investigator selected 80 samples with 40 each in the experimental and control group during all four weeks of data collection.

3.9 CRITERIA FOR SAMPLE SELECTION

3.9.1 Inclusion Criteria

1. Patients who were between the age group of 20 to 70 years.
2. Patients who were fully conscious.
3. Patients who had first time experience to cardiac surgeries (CABG or OPCAB or valve surgery).
4. Patients who had mediastinal chest tube with atleast one pleural chest tube in-situ at the time of chest tube removal.
5. Patients who were extubated from mechanical ventilators and were hemodynamically stable.
6. Patients who were willing to participate in the study.

3.9.2 Exclusion Criteria

1. Patients who were having BMI > 30 kg/m^2.
2. Patients who were over sensitive to cold.
3. Patients who had received Opioid analgesics within 4 hours prior to chest tube removal.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

3.10.1 Section A: Assessment tool

Assessment tool consists of four parts

Part I- Demographic variables which consisted of age, gender, educational qualification and occupation. The questions had multiple options and the investigator collected the responses by interview method.

Part II- Clinical variables which consisted of body mass index which was calculated using weight in kilograms divided by height in meter square. Based on the BMI the subjects were classified into four groups: BMI<18 (under weight), BMI-18-22.9 (normal), BMI-23-24.9 (over weight) and BMI-25-29.9 (class I obesity) as per ICMR recommendations. Standardized electronic weighing scale (done by the hospital routinely) and inch tape were used.

Responses for history of previous surgeries were collected by interview method with questionnaire which had multiple options. The nature of cardiac surgery undergone, total number of chest tubes, size of chest tube and indwell time of chest tube were collected by direct observation method and from patient records.

Part III-Modified Comfort Scale for assessing the level of pain distress

The assessment of patients level of pain distress was done using Modified comfort scale which consisted of 8 dimensions, namely

1. Alertness
2. Physical movement
3. Calmness
4. Facial tension
5. Heart rate
6. Respiratory rate

7. Blood pressure
8. SpO_2

The 8 dimensions were broadly classified into observed physical and observed physiological parameters. Each dimension was observed after 2 minutes of observation of patient's entire body, face and the vital parameters using the cardiac monitor.

Part IV- Visual Analogue Scale (VAS) for assessing level of pain intensity

Patients were instructed to point onto a horizontal line of length 100 mm between two end points in which the far left end indicated **'No pain'** and the far right end indicated **'Worst pain ever'**; which indicated the intensity of pain felt.

SCORING PROCEDURE

1. Modified Comfort Scale for assessing level pain distress

The researcher reviewed patient's bedside medical flow chart and calculated the baseline, upper and lower limits for the parameters like heart rate, blood pressure, respiratory rate and SpO_2. For all of these parameters the values of the preceding 24 hours was taken as the baseline sign. Values 15% above and below were calculated before the observation was made for rapid assessment. The researcher observed the patient from the location where the patient's entire body, face and vital signs monitor was visible. Each dimension was scored from 1 to 5 and the total comfort score was derived as the total of the scores of the eight dimensions.

Each dimensions scoring is mentioned below:

Alertness

The researcher rated patient's response to ambient stimulation in the environment including responses to sound (noises from monitors, intercoms, people talking, etc). The researcher observed alertness of the patient which was scored from 1 to 5 for the criteria's namely deeply asleep (1), lightly asleep (2), drowsy (3), alert (4) and awake and hyper-alert (5).

Physical movement

The researcher rated the frequency and intensity of physical movement from 1 to 5 for the criteria's namely none (1); occasional, slight movements (2); frequent, slight

movements (3); vigorous movements of extremities (4) and vigorous movements of extremities along with torso and head (5).

Calmness

The researcher rated calmness based on the patient's level of emotional arousal and anxiety from 1 to 5 for the criteria's namely calm (1), slightly anxious (2), anxious (3), very anxious (4) and panicky (5).

Facial tension

The researcher assessed the facial tension of the patient by assessing the tone and tension of facial muscles from 1 to 5 for the criteria's namely totally relaxed (1), normal and no evident facial muscle tension (2), tension evident in some facial muscles (3), tension evident throughout facial muscles (4) and facial muscles contorted and grimacing (5).

Heart rate

The heart rate was scored based on the frequency of elevations above baseline. The researcher observed and recorded heart rate for 5-6 times during two minutes of observation period. Ratings were made based upon the number of readings above the baseline from 1 to 5 for the criteria's namely heart rate below baseline (1), heart rate consistently at baseline (2), infrequent elevations of 15% or more (1-3 during observation period) (3), frequent elevations of 15% or more (more than 3 during observation period) (4) and sustained elevation greater than or equal to 15% (5).

Respiratory rate

The respiratory rate was scored based on the frequency of elevations above baseline. The researcher observed and recorded respiratory rate for 5-6 times during two minutes of observation period. Ratings were made based upon the number of readings above the baseline from 1 to 5 for the criteria's namely respiratory rate below baseline (1), respiratory rate consistently at baseline (2), infrequent elevations of 15% or more (for 1-3 times during observation period) (3), frequent elevations of 15% or more (more than 3 during observation period) (4) and sustained elevation greater than or equal to 15% (5).

Blood pressure

Blood pressure was recorded based on the frequency of elevations above baseline. At the beginning of the rating period, baseline, below baseline and above baseline values were recorded. The researcher observed the monitor for 5-6 times during the two minute observation. Ratings were made based upon the number of readings above the baseline from 1 to 5 for the criteria's namely blood pressure below baseline (1) blood pressure consistently at baseline (2), infrequent elevations of 15% or more (1-3 during observation period) (3), frequent elevations of 15% or more (more than 3 during observation period) (4) and sustained elevation greater than or equal to 15% (5).

SpO_2

SpO_2 was recorded based on the frequency of elevations above baseline. At the beginning of the rating period, baseline, below baseline and above baseline values were recorded. The researcher observed the monitor for 5-6 times during the two minute observation. Ratings were made based upon the number of readings above the baseline from 1 to 5 for the criteria's namely SpO_2 above baseline (1), SpO_2 consistently at baseline (2), infrequent decrease of 15% or more (1-3 during observation period) (3), frequent decrease of 15% or more (more than 3 during observation period) (4) and sustained decrease greater than or equal to 15% (5).

Each dimension was scored between 1 and 5 after 2 minutes of observation of patient's entire body, face and the vital parameters using the cardiac monitor. The total comfort score was derived as the total of the scores of all 8 dimensions out of 40, higher the score higher the level of pain distress.

The scores were interpreted as follows

SCORE	INFERENCE
1-8	No distress
9-16	Mild distress
17-24	Moderate distress
25-32	Severe distress
33-40	Very severe distress

2. Visual Analogue Scale (VAS) for assessing level of pain intensity

The VAS score was determined by measuring the millimeters from the left hand end of the line to the point that the patient pointed and which was scored as:

No pain (0–4 mm)
Mild pain (5-44 mm)
Moderate pain (45–74 mm)
Severe pain (75–100 mm)

3.10.2 Section B: Intervention tool

Cryotherapy in this study refers to the application of cooling gel pack, it is a portable plastic sac filled with a refrigerant gel. They are non-toxic, reusable and non-mutagenous in nature. Gel packs are made of hydroxyethyl cellolose, sodium polyacrylate or vinyl- coated silica gel. The cooling gel packs are available in the standard durable laminated plastic pouch made of "no-sweat" paper material to protect against condensation touching the product.

The blue cooling gel packs which were used in this study is capable of maintaining the temperature between +2 to+8°C. For cryotherapy the cooling gel packs used in this study were placed in the refrigerator for up to an hour, to achieve the desired cooling effect. The patient was made to lie down in supine position with the head end elevated to 30°**.** The cooling gel packs used in this study were flexible and it confined well to body parts especially around the chest tube as they were also available in horse shoe shape so that they could cover around tubes easily. This leads to an effective cooling of the tissues around the chest tube site. Sterile gauze was used between the cooling gel packs and the skin surface to prevent frostbite. It was applied around the chest tube for a period of 15 minutes, later which the cooling gel packs were removed and the chest tube was removed according to the hospital routine.

These cooling gel packs as they were reusable, the researcher applied it around the chest tube insertion site for the patients wrapped with sterile gauze. It was sterilized each time after its use by ethylene oxide sterilizer before using it for another patient. Ethylene Oxide (EtO) sterilization is mainly used to sterilize medical and pharmaceutical products that cannot support conventional high temperature steam sterilization - such as devices that incorporate electronic components, plastic packaging or plastic containers.

Hence the researcher had maintained the sterility of the cooling gel packs each time before its application thus preventing any chance for infection or cross infection.

3.11 VALIDATION OF THE TOOL

Content validity is the degree to which the items in the instrument adequately represent the content for the concept being measured. Content validity of the instruments was established by panel of experts comprising in the field of cardio vascular surgery, anaesthesia, medical surgical nursing and statistics. The experts suggestions were incorporated in designing the final tool for the study in consultation with guide, co-guide, experts, ethical committee members and statistician for its appropriateness.

The content validity of the data collection tool and intervention protocol was ascertained from the expert's opinion in the following field of expertise.

Cardio-Thoracic Surgeon	-	1
Anesthetist	-	1
Nursing experts (Educational setup)	-	3

All the experts had their consensus and then the tool was finalized.

3.12 ETHICAL CONSIDERATION

Ethics is a system of moral values that is concerned with the degree to which the research procedures adhere to the professional, legal and social obligations to the study participants.

The study was carried out after obtaining an ethical clearance from the ethical committee of MMM Hospital. The following ethical principles were followed and adhered in the course of study by the researcher.

Ethical principle	Action carried out
Principle of beneficence	The study was done to reduce the pain during chest tube removal among the cardiac post operative patients using cooling gel pack.
Principle of respect for human dignity	Those who were willing to participate were selected as samples for the study and right to withdraw was ensured before data collection.
Principle of confidentiality	The information regarding the samples and their performance were kept confidential.
Principle of informed consent	Informed consent was obtained from all the samples selected for the study.

3.13 PILOT STUDY

The pilot study was conducted once after acquiring the ethical committee clearance from the Madras Medical Mission Hospital. For conducting the study a formal written permission was sought from the Director of Cardio thoracic surgery and the Nursing superintendent of the hospital.

The pilot study was conducted at ICU-III in MMM hospital where on an average basis about 2 to 3 patients underwent chest tube removal each day. The researcher selected the cardiac post operative patients who fulfilled the sample selection criteria out of the total postoperative cardiac patients with chest tube in ICU-III. Out of which 8 samples were selected using simple random sampling (lottery) method. The participants for whom the lot **E** was taken were allocated to the experimental group (n=4) and lot **C** was allocated to the control group (n=4). The physician ordered for chest tube removal within 24 - 48 hours after surgery based on the level of drain and hemodynamic stability of the clients. A brief explanation was given on the purpose of the study to the participants; both oral and written consent was obtained from the participants.

The baseline level of pain intensity, pain distress and quality of pain was assessed by using VAS, modified comfort scale and McGill's pain questionnaire respectively. The routine analgesic administered in the hospital was Inj.Perfelgan which was given to the patients both in the experimental and control group 30 minutes

before the chest tube removal. The investigator had carried out the application of cooling gel pack for 15 minutes prior to the chest tube removal along with the hospital routine for the experimental group whereas for the control group only hospital routine was administered before chest tube removal. Post test level of pain was assessed twice for both the groups within 5 minutes and 20 minutes after the chest tube removal as post test I and post test II using visual analogue scale, modified comfort scale. The data obtained was coded and edited to fit in to the master sheet. The analysis of the pilot study showed statistical significance at $p<0.05$. After the pilot study, the tools such as VAS for assessing the pain intensity, modified comfort scale for assessing the pain distress and cooling gel pack application was found to be reliable, feasible and practicable to conduct the main study. This aided the researcher to check the feasibility of conducting the main study in order to determine the method of statistical analysis and to assess the time required for data collection and intervention in the main study.

3.14 RELIABILITY OF THE TOOL

Reliability is the degree of consistency with which an instrument measures the target attribute for which it was designed to measure. It is the major criterion for assessing the quality and adequacy of an instrument **(Denise F.Polit & Cheryl Tatano Beck, 2008).** The reliability was established during the pilot study using inter-rater method.

The reliability of the tool for assessing the level of pain intensity using **Visual Analogue Scale** was established by inter-rater method and the reliability score was found to be $r = 0.81$ thus indicating that the tool was reliable.

The reliability of the tool for the level of pain distress using **Modified Comfort Scale** was established by inter-rater method and the reliability score was found to be $r = 0.78$ thus indicating that the tool was reliable.

3.15 DATA COLLECTION PROCEDURE

The data collection was conducted after receiving the ethical committee clearance from the Madras Medical Mission hospital. A formal written permission was obtained from the Head of the department of the Cardio thoracic surgery and the Nursing

department to conduct the study. The main study was conducted at adult ICU which is a 23 bedded postoperative cardiac ICU in MMM hospital where on an average basis receives 7 cardiac postoperative patients per day. Permission was also sought from the nursing in charge of AICU for carrying out the study in their setup. The surgery list or the posted list of patients planning for cardiac surgery the next day was obtained a day before from the cardiac operation theatre by the researcher. The main study was conducted on 80 samples.

The researcher selected the cardiac post operative patients who fulfilled the sample selection criteria out of the total postoperative cardiac patients with chest tube in AICU as soon as they were received from cardiac OT. Out of the samples who fulfilled the selection criteria, a total of 80 samples were selected using simple random sampling (lottery) method. The researcher had prepared 80 chits with 40 chits having **'E'** mentioned in it and another 40 chits with **'C'** mentioned in it. The researcher blindly selected a chit in front of the samples, the patients for whom the researcher took lot **E** were allocated to the experimental group (n=40) and those for whom lot **C** was taken were allocated to the control group (n=40). A brief explanation was given on the purpose of the study to the participants after extubation; both written and oral consent was obtained from the patients individually. The patients who belonged to the experimental group were given a clear explanation about the application of 'cooling gel packs' during chest tube removal.The physician ordered for chest tube removal within 24 - 48 hours after surgery based on the level of drain and hemodynamic stability of the clients. Data collection was carried out in 3 phases namely assessment phase, intervention phase and follow up phase.

Assessment phase

In the assessment phase, data collection was started with an introduction of the researcher. The demographic and clinical characteristics were collected. The researcher assured the clients about the anonymity and the confidentiality. After gaining confidence the patients were made to feel comfortable and the baseline assessment of pain distress and pain intensity was done using modified comfort scale and VAS, 30 minutes prior to CTR for 2-5 minutes.

Intervention phase

This phase begins once after the physician ordered for CTR the samples in the experimental group were administered Inj. Perfalgan (Hospital routine) 30 minutes before CTR. The patients were made to lie down in supine position with the head end elevated to 30° and a sterile gauze barrier was used between the cooling gel pack and the skin surface around the chest tube insertion site in order to prevent frostbite following the hospital routine. Cooling gel packs were applied around the chest tube site for 15 minutes prior to CTR. For the control group all the above was followed except for the application of cooling gel pack. Immediately after which the chest tube was removed as per the hospital routine.

Follow up phase

In the final phase of data collection post test –I assessment on the level of procedural pain was assessed within 5 minutes after CTR using VAS to assess the pain intensity and modified comfort scale to assess the pain distress levels for the experimental and control group. Post test –II assessment on the level of procedural pain was assessed using VAS to assess the pain intensity and modified comfort scale to assess the pain distress levels for both experimental and control group 20 minutes from CTR.

The collected data was organized and tabulated for analysis.

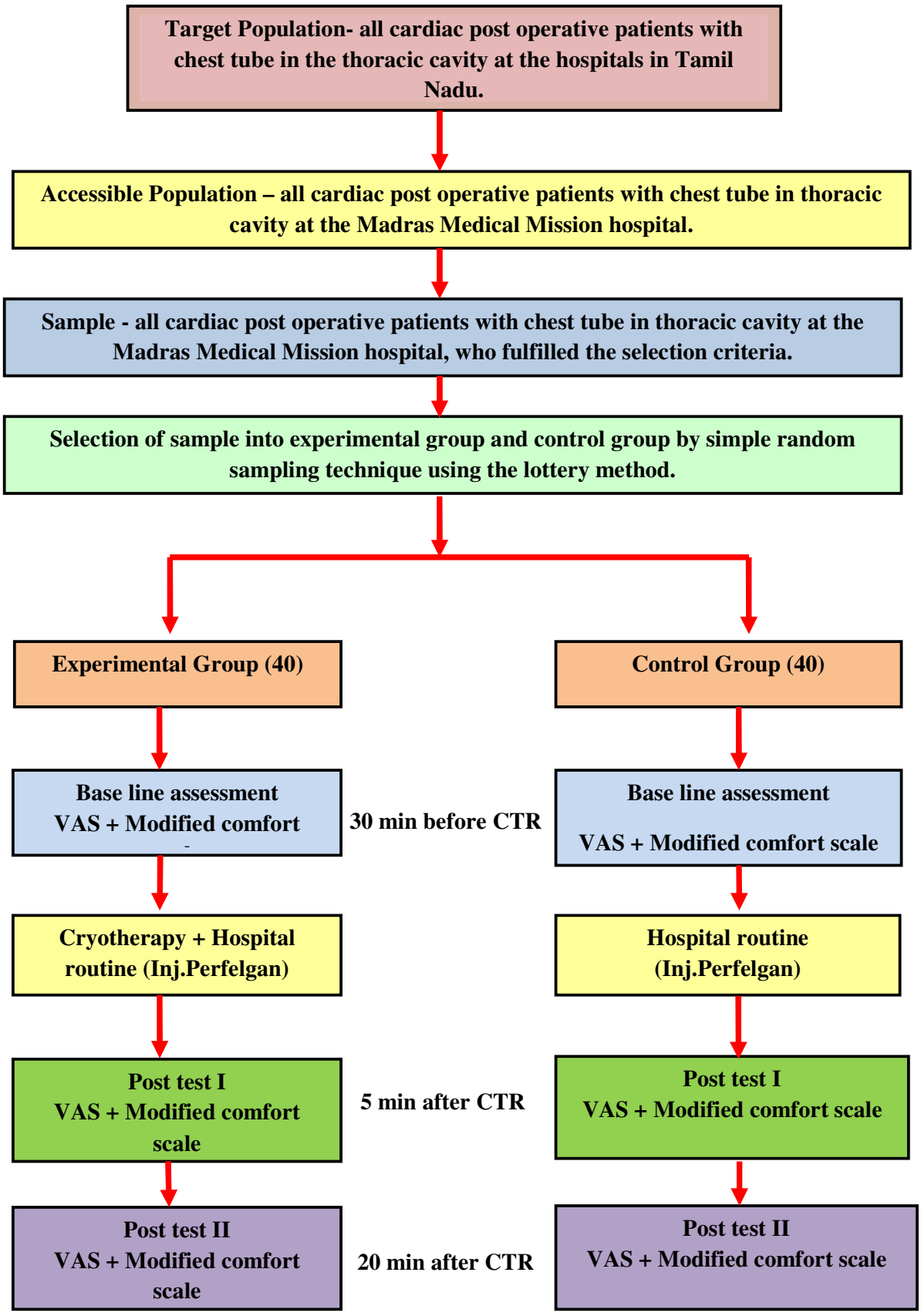

Fig. 3.15.1: Schematic representation of data collection procedure.

PHASES OF DATA COLLECTION PROCEDURE

Phases of data collection	Activity done	Time and duration
Phase I **Assessment Phase**	Baseline assessment was done using VAS and Modified comfort scale including observation of physical and physiological parameters for the patients planned for CTR.	30 minutes before CTR for duration of 2-5 minutes.
Phase II **Intervention phase**	**Experimental group** Application of cryotherapy along with the hospital routine prior to CTR. **Control group** Administration of hospital routine prior to CTR.	Cryotherapy for 15 minutes before CTR
Phase III **Follow up phase**	**Post test I** - Level of procedural pain was assessed using VAS and Modified comfort scale including observation of physical and physiological parameters.	Within 5 minutes from CTR for duration of 2-5 minutes.
	Post test II - Assessed level of procedural pain using VAS and Modified Comfort Scale including observation of physical and physiological parameters.	20 minutes from CTR for duration of 2-5 minutes.

3.16 DATA ANALYSIS PROCEDURE

Data analysis is the systematic organization and synthesis of research data and testing the null hypothesis using those data. **(Denise F.Polit & Cheryl Tatano Beck, 2008).** The data was collected from 80 cardiac post operative patients with chest tubes 40 each in experimental and control group. The data obtained was coded and edited to fit in to the master sheet. The data collected was analyzed using both descriptive and inferential statistics.

3.16.1 Descriptive Statistics

1. Frequency and percentage distribution was used to analyse the background variables and level of procedural pain.
2. Mean and Standard deviation was used to assess the level of procedural pain.

3.16.2 Inferential Statistics

1. Unpaired ‘t’ test was used to compare the level of procedural pain between the control group and experimental group.
2. Chi-square test will be used to associate the post test level of pain with selected demographic and clinical variables of experimental group.

DATA ANALYSIS AND INTERPRETATION

CHAPTER – 4

DATA ANALYSIS AND INTERPRETATION

The analysis is a process of organizing and synthesizing the data in such a way that the research questions can be answered and the hypotheses are tested**.**

This chapter deals with the analysis and interpretation of the data collected from 80 cardiac post operative patients to investigate the effectiveness of cryotherapy on procedural pain. The data was organized, tabulated and analyzed according to the objectives. Data analysis begins with description that applies to the study in which the data are numerical with some concepts. Descriptive statistics allows the researcher to organize the data and to examine the quantum of information and inferential statistics used to determine the relationship and causality.

ORGANISATION OF THE DATA

Data collected were organized under the following sections.

Section A: Description of the demographic variables of cardiac post operative patients in the experimental and control group.

Section B: Assessment of procedural pain among the cardiac post operative patients in the experimental and control group.

Section C: Effectiveness of cryotherapy on procedural pain in cardiac post operative patients between the experimental and control group.

Section D: Association of baseline and post test level of procedural pain in cardiac post operative patients with selected demographic and clinical variables in the experimental group.

SECTION A: DESCRIPTION OF DEMOGRAPHIC VARIABLES OF CARDIAC POST OPERATIVE PATIENTS IN THE EXPERIMENTAL AND CONTROL GROUP.

Table 4.1: Frequency and percentage distribution of demographic variables of cardiac post operative patients in the experimental and control group.

N = 80(40+40)

Demographic variables		Group				Chi square test
		Experimental		Control		
		n	%	n	%	
Age in years	20-30 years	04	10.0	06	15.0	χ^2 =2.001 df=4 p= 9.49 N.S
	31-40 years	03	07.5	02	05.0	
	41-50 years	09	22.5	13	32.5	
	51-60 years	15	37.5	11	27.5	
	61-70 years	09	22.5	08	20.0	
Gender	Male	30	75.0	27	67.5	χ^2 =0.549 df=1 p= 3.84 N.S
	Female	10	25.0	13	32.5	
Education	No formal education	03	07.5	03	07.5	χ^2 =1.771 df=4 p= 9.49 N.S
	Primary school	05	12.5	07	17.5	
	High school	09	22.5	11	27.5	
	Higher Secondary	10	25.0	11	27.5	
	Graduate and above	13	32.5	08	20.0	
Occupation	Professional	19	47.5	16	40.0	χ^2 =1.871 df=3 p= 7.82 N.S
	Skilled worker	08	20.0	07	17.5	
	Unemployed	06	15.0	11	27.5	
	Retired	07	17.5	06	15.0	

at p=0.05, N.S - Not Significant

The above table 4.1 depicts the frequency and percentage distribution of demographic variables of cardiac post operative patients in the experimental and control group.

A total of 80 samples participated in the study with 40 in experimental and 40 in the control group. With regard to age, 15(37.5%) of them were in 51-60 yrs age group in experimental group and 13(32.5%) of them were in 41-50 yrs age group in control group. Considering the gender, 30(75%) samples in the experimental group and 27(67.5%) in the control group were males.

Considering education, 13(32.5%) of them were graduate and above and only 3 (7.5%) of them had no formal education in the experimental group. Correspondingly in the control group 11(24.5%) of them had completed high school and higher secondary education and totally 3 (7.5%) of them had no formal education.

Taking into account the occupation, 19(47.5%) of them were professionals and only 6(15%) of them were unemployed in the experimental group. Likewise in the control group 16(40%) of them were professionals and 6(15%) of them were retired.

The above descriptions of demographic variables revealed that there is no significant difference between the experimental and control group. The chi square test also revealed that there is no statistically significant difference between the experimental and control group in relation to the demographic variables which confirms the homogeneity of the samples.

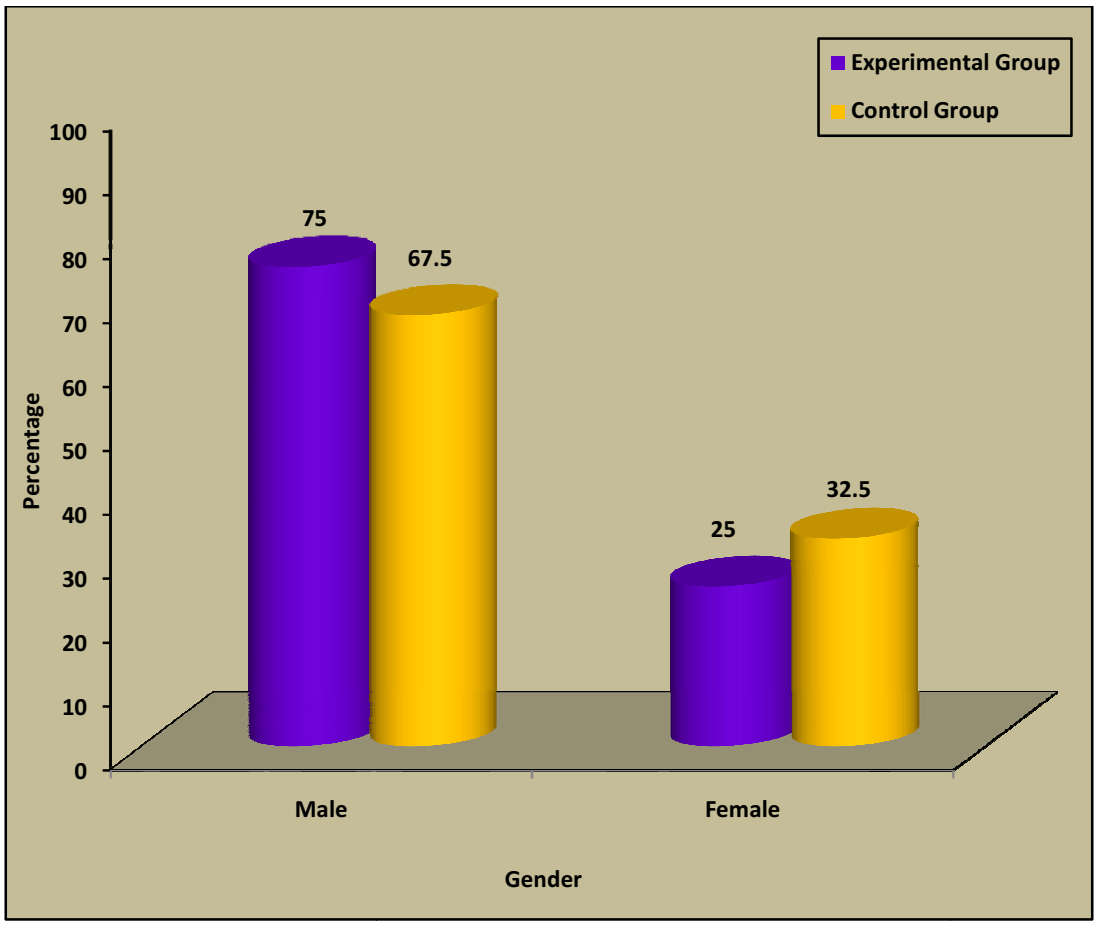

Fig. 4.1: Percentage distribution of gender of the cardiac post operative patients in the experimental and control group

Table 4.2: Frequency and percentage distribution of clinical variables of cardiac post operative patients in the experimental and control group.

N = 80(40+40)

Clinical variables		Group				Chi square test
		Experimental		Control		
		n	%	n	%	
Body Mass Index	18 and less	03	07.5	02	05.0	χ^2 =0.565 df=3 p= 7.82 N.S
	18.1 - 23.0	04	10.0	05	12.5	
	23.1 - 25.0	12	30.0	14	35.0	
	25.1 - 30.0	21	52.5	19	47.5	
History of previous surgeries	Minor	09	22.5	12	30.0	χ^2 =0.648 df=2 p=5.99 N.S
	Major	04	10.0	03	07.5	
	Nil	27	67.5	25	62.5	
Nature of cardiac surgery undergone	Coronary Artery Bypass Graft- On Pump	14	35.0	17	42.5	χ^2 =1.853 df=4 p= 9.49 N.S
	Coronary Artery Bypass - Off Pump	09	22.5	06	15.0	
	Valve repair surgery	08	20.0	07	17.5	
	Valve replacement surgery	09	22.5	10	25.0	
Total number of chest tubes	Two	19	47.5	16	40.0	χ^2 =1.526 df=3 p= 7.82 N.S
	Three	19	47.5	20	50.0	
	Four	02	05.0	04	10.0	
Size of chest tube	28 F	14	35.0	20	50.0	χ^2 =1.980 df=2 p=5.99 N.S
	32 F	21	52.5	17	42.5	
	34 F	05	12.5	03	07.5	

Clinical variables		Group				Chi square test
		Experimental		Control		
		n	%	n	%	
Indwell time of chest tubes	Less than 24 hours	18	45.0	14	35.0	χ^2 =1.296 df=3 p= 7.82 N.S
	24-36 hours	13	32.5	16	40.0	
	37-48 hours	06	15.0	08	20.0	
	More than 48 hours	03	07.5	02	05.0	

at p=0.05, N.S - Not Significant

The above table 4.2 depicts the frequency and percentage distribution of clinical variables of cardiac post operative patients in the experimental and control group.

With respect to Body Mass Index, 21(52.5%) patients in experimental group and 19(47.5%) in control group were having BMI in the range of (25.1 -30); of which 3(7.5%) of them in the experimental and 2(5%) of them in control group had BMI less than 18. Considering the history of surgery, 27(67.5%) in experimental and 25(62.5%) in control group had not undergone any surgery while 9(22.5%) and 12(30%) of them had undergone minor surgery in experimental and control group respectively. 4(10%) patients in experimental group and 3(7.5%) patients in control group had undergone major surgeries.

With view to the nature of cardiac surgery undergone, 14(35%) in experimental group and 17(42.5%) of them in control group had undergone Coronary Artery Bypass Graft- On Pump. Similarly 9(22.5%) in the experimental group and 6(15%) of them in control group had undergone Coronary Artery Bypass - Off Pump. 8 (20%) of the cardiac postoperative patients in the experimental group and 7(17.5%) in control group had undergone valve repair surgery. valve replacement surgery was undergone by 8(20%) and 7(17.5%) patients in experimental and control group respectively.

When considering the total number of chest tubes, 19(47.5%) of them had two as well as three chest tubes in the experimental group. While 16(40%) of them had two chest tubes and 20(50%) of them had three chest tubes in control group. Regarding size of the chest tube,

21(52.5%) of them in the experimental and 17(42.5%) in the control group had 32F while 5(12.5%) of the samples in the experimental group and 3(7.5%) of them in the control group had chest tube of 32F.

Concerning the indwell period of chest tube about 18(45%) patients in experimental group and 14(35%) in control group had indwell period of chest tubes less than 24 hours; 13(32.5%) of them had chest tube for 24-36 hours in experimental group and 16(40%) in the control group had chest tube for 24-36 hours. About 6(15%) patients in experimental and 8(20%) patients in control group were having the chest tubes for 37-48 hours. While 3(7.5%) of the patients in the experimental group and 2(5%) of them in control group had indwell time of chest tube for more than 48 hours.

The study findings revealed that majority of the samples were having BMI in the range of 25.1-30.0 with no history of previous surgeries. Most of the samples had undergone CABG with two or three chest tubes of either 28F or 32F for duration of 36 hours of indwell in both the experimental and control group. This indicated that there is no difference between the experimental and control group. The chi square test revealed that there was no statistically significant difference between the experimental and control group in relation to the clinical variables which established the homogeneity of the samples.

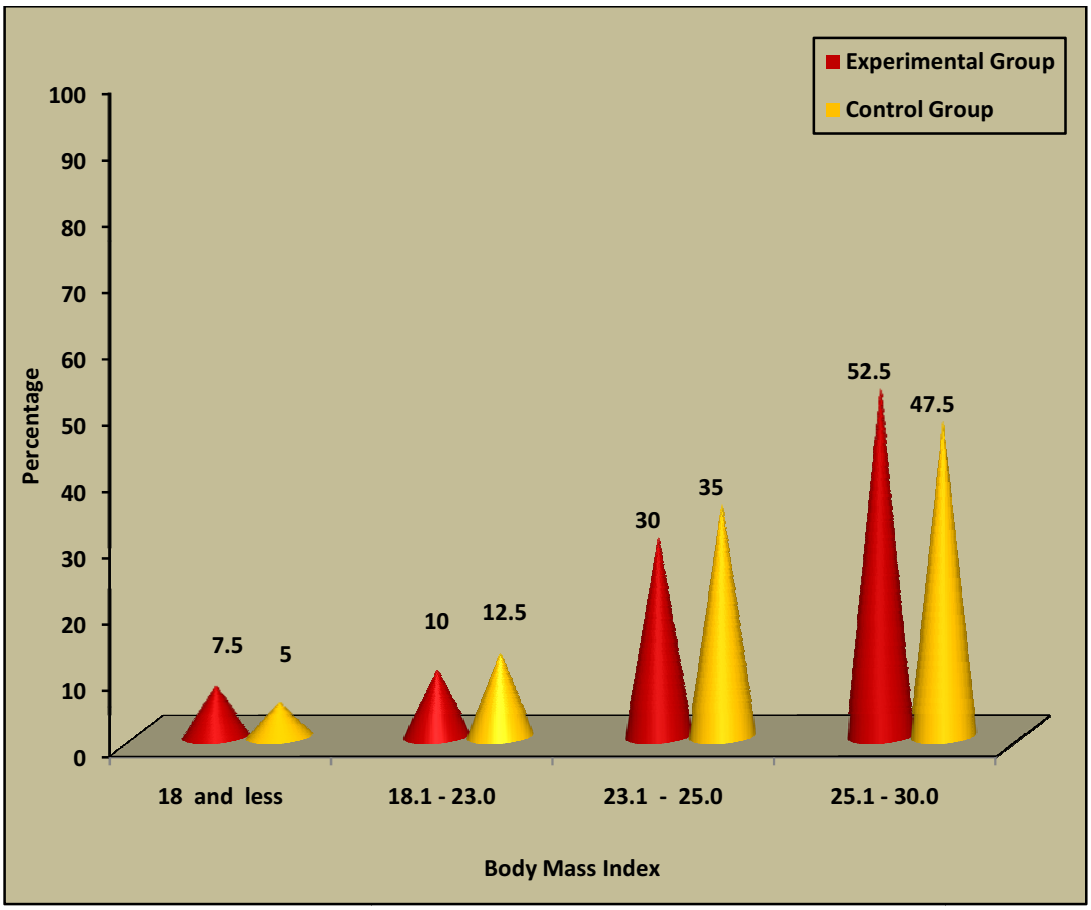

Fig. 4.2: Percentage distribution of body mass index of the cardiac post operative patients in the experimental and control group.

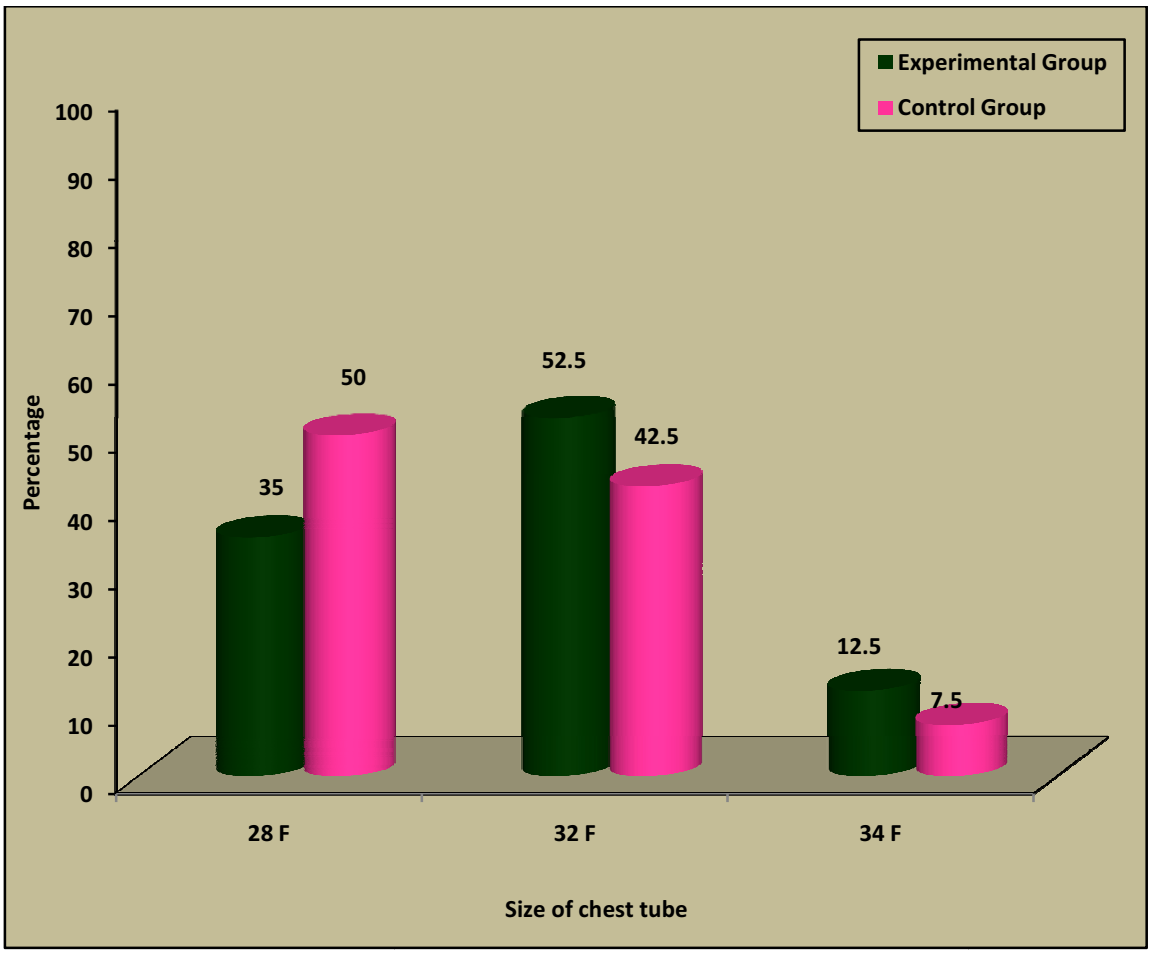

Fig. 4.3: Percentage distribution of size of chest tube of the cardiac post operative patients in the experimental and control group.

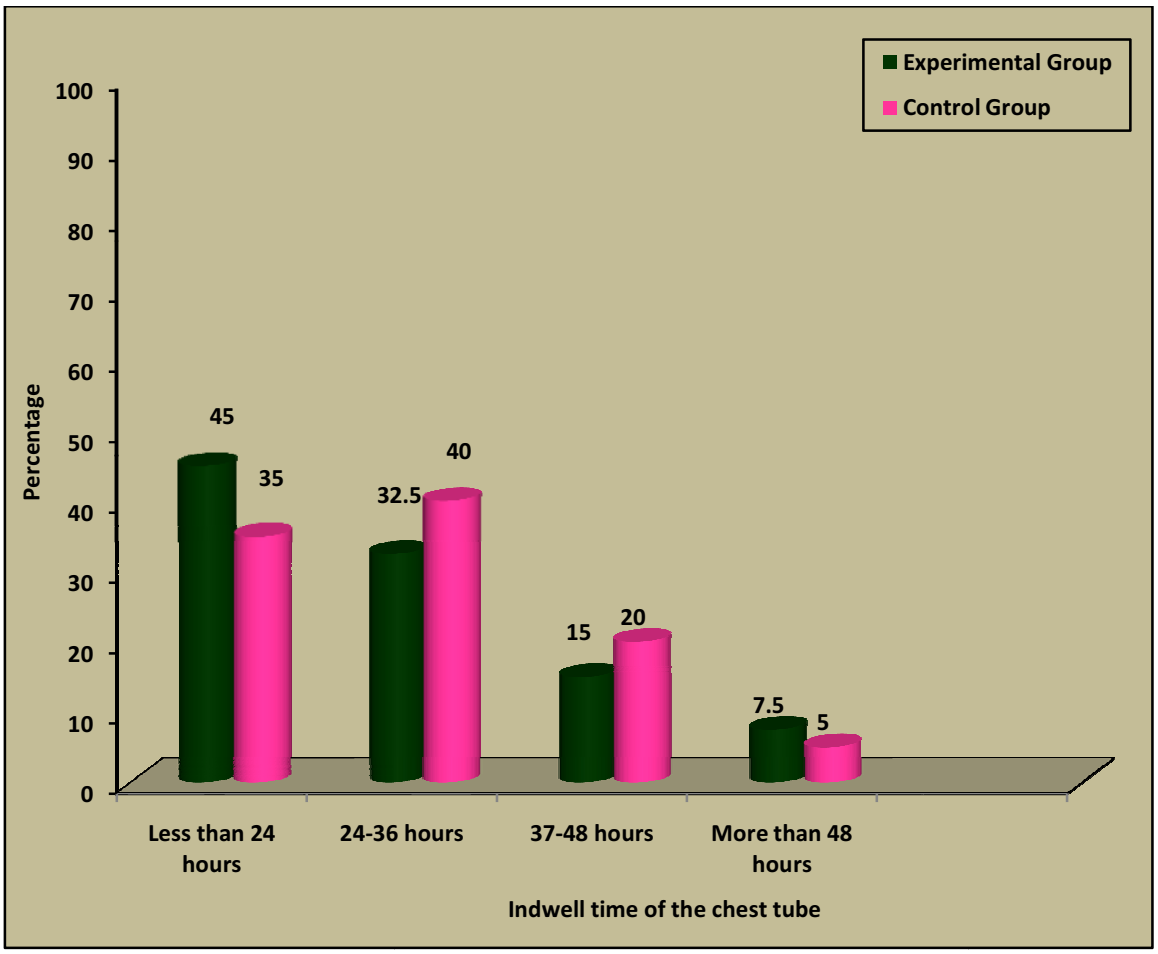

Fig. 4.4: Percentage distribution of indwell time of chest tubes by the cardiac post operative patients in the experimental and control group.

SECTION B: ASSESSMENT OF PROCEDURAL PAIN AMONG THE CARDIAC POST OPERATIVE PATIENTS IN THE EXPERIMENTAL AND CONTROL GROUP.

Table 4.3: Frequency and percentage distribution of pain distress of the cardiac post operative patients in the experimental and control group.

N = 80(40+40)

Group	Level of Pain Distress	Baseline		Post-test I		Post-test II	
		n	%	n	%	n	%
Experimental	No distress	00	00.0	00	00.0	00	00.0
	Mild distress	10	25.0	00	00.0	34	85.0
	Moderate distress	30	75.0	00	00.0	06	15.0
	Severe distress	00	00.0	26	65.0	00	00.0
	Very severe distress	00	00.0	14	40.0	00	00.0
Control	No distress	00	00.0	00	00.0	00	00.0
	Mild distress	50	12.5	00	00.0	14	35.0
	Moderate distress	35	87.5	00	00.0	26	65.0
	Severe distress	00	00.0	00	00.0	00	00.0
	Very severe distress	00	00.0	40	100	00	00.0
Chi square test		**X^2=2.051 df=1 p= 3.84 N.S**		X^2=38.519 df=1 p= 3.84* S		X^2=20.833 df=1 p= 3.84* S	

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The above table 4.3 depicts the frequency and percentage distribution of the pain distress level of cardiac post operative patients in the experimental and control group.

The baseline level of pain distress in the experimental group revealed that 10(25%) of them had mild pain distress and 30(75%) of them had moderate pain distress. Whereas in control group 5(12.5%) of them had mild pain distress and 35(87.5%) of them had moderate pain distress. None of patients had been without any pain distress, severe and very severe pain distress both in experimental and control group at baseline level.

This specifies that there was no difference in the level of pain distress on baseline assessment between the experimental and control group which depicted the homogeneity of the samples.

The post test I level of pain distress on evaluation showed that 26(65%) of them had severe pain distress and 14(40%) of them had very severe pain distress in the experimental group whereas all 40(100%) of them had very severe pain distress in the control group.

The post test II level of pain distress showed that 34(85%) and 6(15%) of them in the experimental group had mild and moderate pain distress level respectively. But in control group 14(35%) and 26(65%) of them had mild and moderate pain distress level respectively.

No significant difference in the baseline level of pain distress between the experimental and control group was interpreted from the above findings. It was evident from the above data that the cardiac post operative patients both in experimental and control group had certain amount of pain distress even before the chest tube removal which was measured as baseline pain distress level.

The post test I findings revealed that samples from both the experimental and control group experienced very severe pain distress but there was significant difference between both of them demonstrating the effect of cryotherapy (cooling gel pack). In the post test II the pain distress had comparatively reduced in both the experimental and control group but a significant difference was noted between the two groups indicating the sustained effect of the cooling gel pack on the procedural pain distress level of the experimental group.

Table 4.4: Mean and Standard deviation of pain distress level of the cardiac post operative patients in the experimental and control group.

N = 80(40+40)

Group	Baseline		Post-test I		Post-test II	
	Mean	**S.D**	**Mean**	**S.D**	**Mean**	**S.D**
Experimental	18.10	2.023	31.65	2.607	14.90	1.892
Control	18.30	1.572	35.03	1.209	17.78	1.928

The above table 4.4 shows mean and S.D of Pain distress level of the cardiac post operative patients in the experimental and control group

The baseline mean score of pain distress among the experimental group was revealed to be 18.10 with S.D of 2.023 where as in the posttest I the mean score of pain distress was 31.65 with S.D of 2.607; post test II level of mean score on pain distress was 14.90 with S.D of 1.892. The baseline mean score of pain distress among the control group was 18.30 with the S.D of 1.572 where as in the post test I the mean score of pain distress was 35.03 with the S.D of 1.209 and post test II level of mean score on pain distress was 17.78 with the S.D of 1.928.

The mean pain distress score had increased from the baseline in the post test I both in experimental and control group as an impact of the procedure, but this increase was found to be more in the control group than the experimental group. There is significant decline in the mean pain distress scores of both the experimental and control group in the post test II but this decline in pain distress level was found to be more in the experimental group than the control group this which in turn indicated the effectiveness of cryotherapy on the procedural pain.

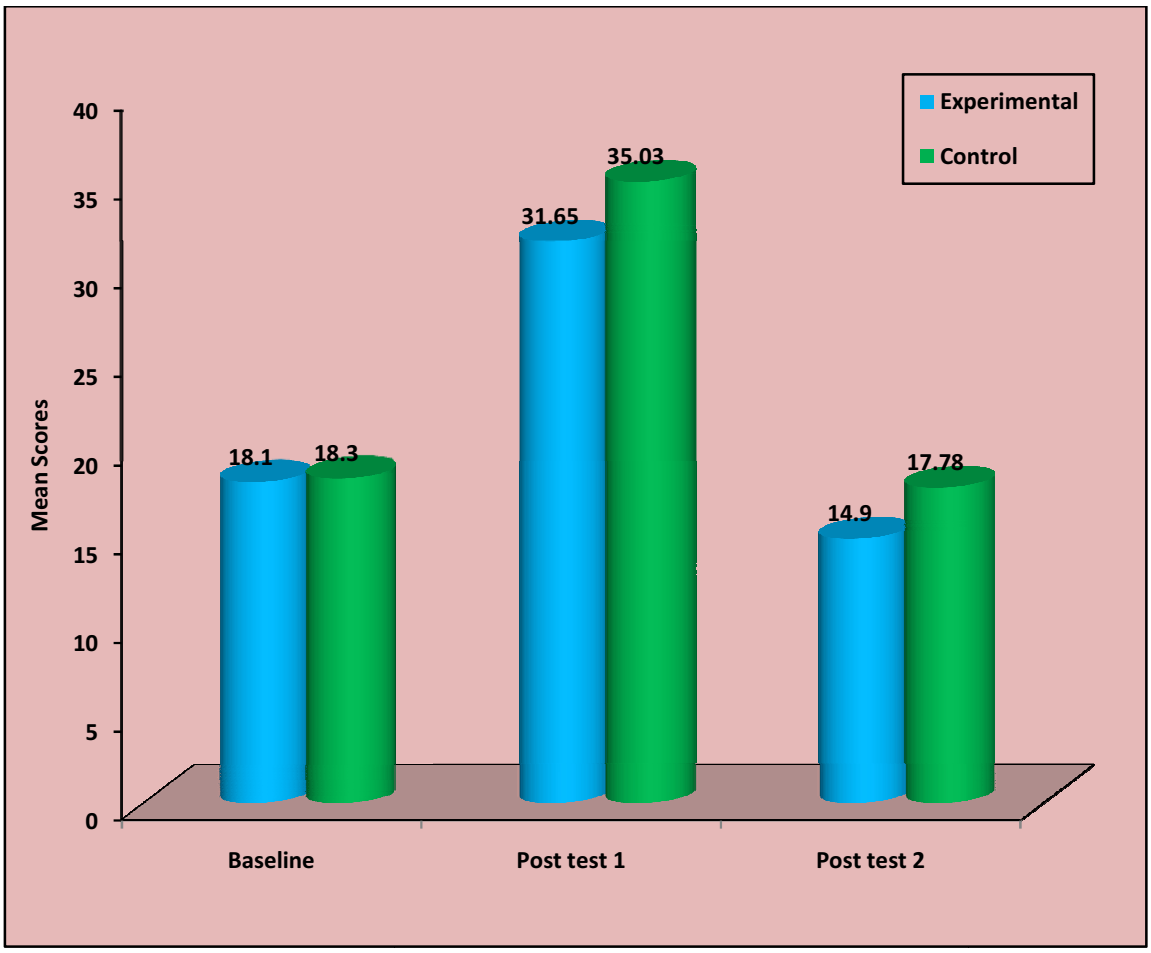

Fig. 4.5: Comparison of pain distress between the experimental and control group.

Table 4.5: Frequency and percentage distribution of pain intensity of the cardiac post operative patients in the experimental and control group.

N = 80(40+40)

Group	Level of Pain Intensity	Baseline		Post-test I		Post-test II	
		n	%	n	%	n	%
Experimental	No pain	00	00.0	00	00.0	00	00.0
	Mild pain	13	32.5	00	00.0	20	50.0
	Moderate pain	27	67.5	01	02.5	20	50.0
	Severe pain	00	00.0	39	97.5	00	00.0
Control	No pain	00	00.0	00	00.0	00	00.0
	Mild pain	12	30.0	00	00.0	05	12.5
	Moderate pain	28	70.0	00	00.0	35	87.5
	Severe pain	00	00.0	40	100	00	0.00
Chi square test		**χ^2 =0.058 df=1 p= 3.84 N.S**		χ^2 =1.013 df=1 p= 3.84 N.S		χ^2 =13.091 df=1 p= 3.84* S	

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The above table 4.5 depicts the frequency and percentage distribution of the pain intensity level of cardiac post operative patients in the experimental and control group.

The baseline level of pain intensity in the experimental group showed that 13(32.5%) of them had mild pain and 27(67.5%) of them had moderate pain. Whereas in control group 12(30%) had mild pain and 28(70%) of them had moderate pain. At baseline level none of patients had either experienced no pain or severe pain in both the experimental and control group. This denoted that there is no difference between the two groups in the level of pain intensity on the baseline assessment performed, which establishes the homogeneity of the samples.

The post test I level of pain intensity on assessment demonstrated that 1(2.5%) of them had moderate pain and 39(97.5%) of them had severe pain in the experimental group whereas all 40(100%) of them had severe pain in the control group.

The post test II level of pain intensity revealed that 20(50%) samples in the experimental group had mild pain intensity and 20(50%) of them had moderate pain intensity whereas in the control group only 5(12.5%) of them had mild pain intensity and 35(87.5%) of them had moderate pain intensity.

The above data makes it evident that the cardiac post operative patients both in experimental and control group had certain amount of pain even before the chest tube removal which was measured as baseline pain level and there was no statistically significant difference in the level of pain intensity between the experimental and the control group proving the homogeneity of the samples of two groups.

Table 4.6: Mean and standard deviation of pain intensity of cardiac post operative patients among the experimental and control group.

N = 80(40+40)

Group	Baseline		Post-test I		Post-test II	
	Mean	**S.D**	**Mean**	**S.D**	**Mean**	**S.D**
Experimental	48.55	7.056	84.90	4.744	44.75	7.037
Control	48.38	7.379	89.45	3.796	51.73	6.496

The above table 4.6 shows mean and S.D of pain intensity level of the cardiac post operative patients in the experimental and control group

The baseline mean score of pain intensity among the experimental group was revealed to be 48.55 with the S.D of 7.056 where as in the posttest I the mean score of pain intensity was 84.90 with the S.D of 4.744; post test II level of mean score on pain intensity was 44.75 with the S.D of 7.037.The baseline mean score of pain intensity among the control group was 48.38 with the S.D of 7.379 where as in the post test I the mean score of pain intensity was 89.45 with the S.D of 3.796 and post test II level of mean score on pain intensity was 51.73 with the S.D of 6.496.

The mean pain intensity score findings revealed that there was increases in the pain intensity from the baseline to post test I for both the experimental and control group as an impact of the procedure, but this increase was found to be more in the control group than the experimental group. There was a significant decline in the mean pain intensity scores of both the experimental and control group in the post test II but this decline in pain intensity level was found to be more in the experimental group than the control group which came down even less than its baseline pain intensity level that indicated the effectiveness of cryotherapy on the procedural pain.

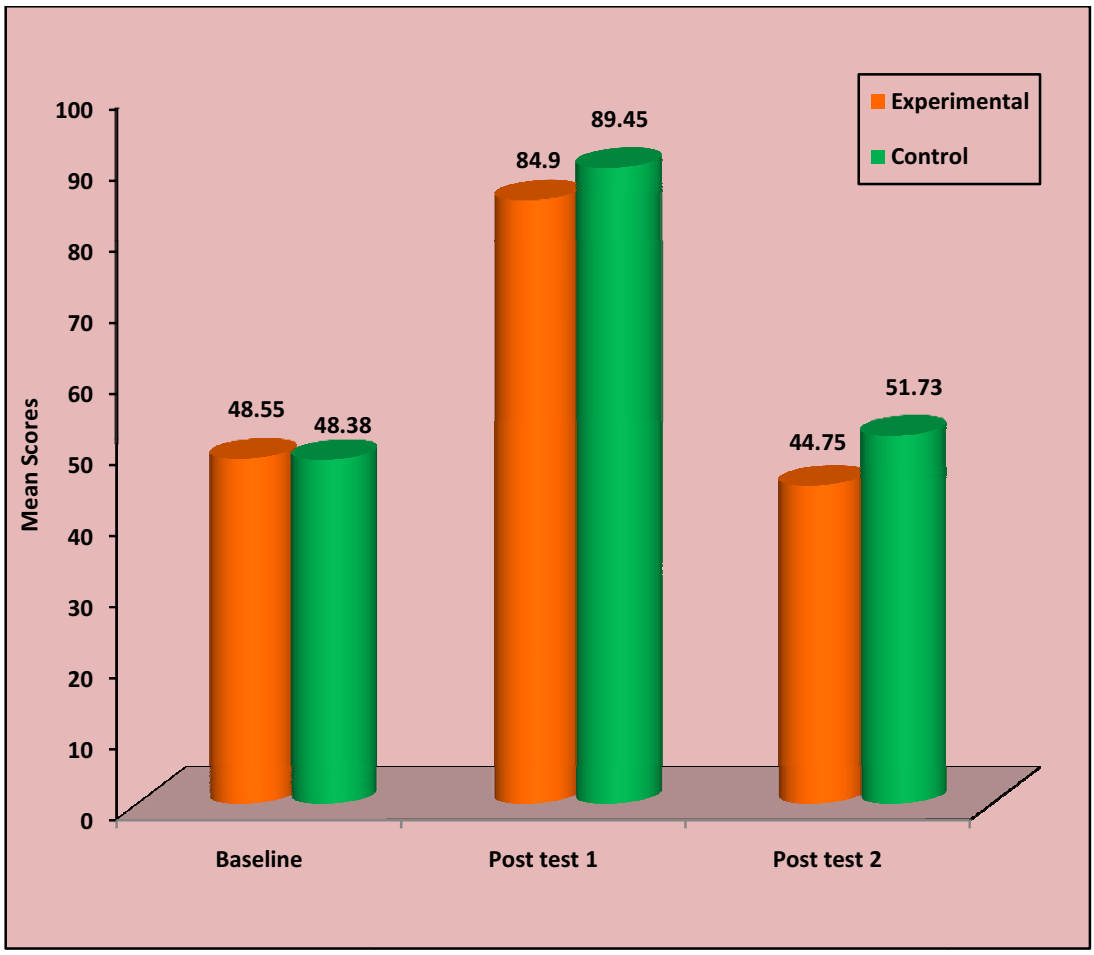

Fig. 4.6: Comparison of pain intensity between the experimental and control group.

SECTION C: ASSESSMENT OF EFFECTIVENESS OF CRYOTHERAPY ON PROCEDURAL PAIN AMONG THE CARDIAC POST OPERATIVE PATIENTS IN EXPERIMENTAL AND CONTROL GROUP.

Table 4.7: Comparison of pain distress between the experimental and control group.

N=80(40+40)

Group	Baseline		Post test I		Post test II	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Experimental	18.10	2.023	31.65	2.607	14.90	1.892
Control	18.30	1.572	35.03	1.209	17.78	1.928
Unpaired 't' test	t = 0.494 df = 78 p=1.990 N.S		**t = 7.428** **df = 78** **p=1.990*** **S**		**t = 6.731** **df = 78** **p=1.990*** **S**	

***Significant at p=0.05, N.S - Not Significant, S – Significant**

The above table 4.7 describes the comparison of pain distress level between experimental and control group.

Taking into consideration the baseline pain distress, the mean score was 18.10 with the SD of 2.023 in the experimental group and in the control group the mean score was 18.30 with the SD of 1.572. With regard to the post test I pain distress, the mean score was 31.65 with the SD of 2.607 in the experimental group and in the control group the mean score was 35.03 with the SD of 1.209. With respect to the post test II pain distress, the mean score was 14.90 with the SD of 1.892 in the experimental group and in the control group the mean score was 17.78 with the SD of 1.928.

The student unpaired 't' test disclosed that there is no statistical significant difference in the base line pain distress between the experimental and the control group which indicated the homogeneity of the samples.

The students unpaired ‘t’ test revealed that there is statistically significant difference between the experimental group and control group in post test I with **t= 7.428 at p=0.05** level which proved that cryotherapy had significant impact on reducing the procedural pain distress level among the cardiac postoperative patients.

The students unpaired ‘t’ test also revealed that there is statistically significant difference between the experimental group and control group in post test II with **t= 6.731 at p=0.05** level which proved that cryotherapy had sustained significant impact on reducing the procedural pain distress level among the cardiac postoperative patients.

The study findings revealed that cryotherapy had immediate and sustained effect on reducing the level of procedural pain distress among the cardiac postoperative patients.

Table 4.8: Comparison of pain intensity between the experimental and control group.

N= 80(40+40)

Group	Baseline		Post test I		Post test II	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Experimental	48.55	7.056	84.90	4.744	44.75	7.037
Control	48.38	7.379	89.45	3.796	51.73	6.496
Unpaired 't' test	t= 0.108 df=78 p=1.990 NS		**t= 4.737 df=78 p=1.990* S**		**t= 4.606 df=78 p=1.990* S**	

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The above table 4.8 describes the comparison of pain intensity level between experimental and control group.

The baseline pain intensity revealed the mean score of 48.55 with the SD of 7.056 in the experimental group and in the control group the mean score was 48.38 with the SD of 7.379. With respect to the post test I pain intensity, the mean score was 84.90 with the SD of 4.744 in the experimental group and in the control group the mean score was 89.45 with the SD of 3.796. With respect to the post test II pain intensity, the mean score was 44.75 with the SD of 7.037 in the experimental group and in the control group the mean score was 51.73 with the SD of 6.496.

The student unpaired 't' test revealed that there was no statistically significant difference in the base line pain intensity between the experimental and the control group which indicated the homogeneity of the samples.

The students unpaired 't' test revealed that there is statistically significant difference between the experimental group and control group in post test I with **t= 4.737 at p=0.05** level which proved that cryotherapy had significant impact on reducing the procedural pain intensity among the cardiac postoperative patients.

Statistically significant difference was revealed between the experimental and control group using the students unpaired ‘t’ test with **t= 4.606 at p=0.05** level which proved that cryotherapy had sustained significant impact on reducing the procedural pain intensity among the cardiac postoperative patients.

The study findings revealed that cryotherapy had immediate and sustained effect on reducing the level of procedural pain intensity among the cardiac postoperative patients.

SECTION D: ASSOCIATION OF SELECTED DEMOGRAPHIC AND CLINICAL VARIABLES WITH THE PROCEDURAL PAIN AMONG THE CARDIAC POST OPERATIVE PATIENTS IN THE EXPERIMENTAL GROUP.

Table 4.9: Association of selected demographic variables with the post test I pain distress levels in the experimental group. N= 40

S. No	Demographic Variables	No Distress		Mild Distress		Moderate Distress		Severe Distress		Very Severe Distress		Chi-Square Value
		n	%	n	%	n	%	n	%	n	%	
1	**Age in years**											
	20-30 years	00	00.0	00	00.0	00	00.0	03	07.5	01	02.5	χ^2 =1.343
	31-40 years	00	00.0	00	00.0	00	00.0	02	05.0	01	02.5	df=4
	41-50 years	00	00.0	00	00.0	00	00.0	07	17.5	02	05.0	p= 9.49
	51-60 years	00	00.0	00	00.0	00	00.0	09	22.5	06	15.0	N.S
	61-70 years	00	00.0	00	00.0	00	00.0	05	12.5	04	10.0	
2	**Gender**											χ^2 =1.319
	Male	00	00.0	00	00.0	00	00.0	18	45.0	12	30.0	df=1
	Female	00	00.0	00	00.0	00	00.0	08	20.0	02	02.5	p= 3.84
												N.S
3	**Education**											
	No formal education	00	00.0	00	00.0	00	00.0	03	07.5	00	00.0	χ^2 =3.284
	Primary school	00	00.0	00	00.0	00	00.0	04	10.0	01	02.5	df=4
	High school	00	00.0	00	00.0	00	00.0	05	12.5	04	10.0	p= 9.49
	Higher Secondary	00	00.0	00	00.0	00	00.0	07	17.5	03	07.5	N.S
	Graduate and above	00	00.0	00	00.0	00	00.0	07	17.5	06	15.0	
4	**Occupation**											
	Professional	00	00.0	00	00.0	00	00.0	10	25.0	09	22.5	χ^2 =5.783
	Skilled worker	00	00.0	00	00.0	00	00.0	08	20.0	00	00.0	df=3
	Unemployed	00	00.0	00	00.0	00	00.0	04	10.0	02	05.0	p= 7.82
	Retired	00	00.0	00	00.0	00	00.0	04	10.0	03	07.5	N.S

***Significant at p=0.05, N.S - Not Significant**

The table 4.9 shows the association of selected demographic variables with the post test I levels of pain distress among the cardiac postoperative patients in the experimental group.

No statistically significant association found between the post test I levels of pain distress and the demographic variables such as age, gender, education and occupation in the experimental group.

Table 4.10: Association of selected clinical variables with the post test I pain distress levels in the experimental group. N= 40

S. No	Clinical Variables	No Distress		Mild Distress		Moderate Distress		Severe Distress		Very Severe Distress		Chi-Square Value
		n	%	n	%	N	%	n	%	n	%	
1	**Body Mass Index**											χ^2 =4.574 df=3 p= 7.82 N.S
	18 and less	00	00.0	00	00.0	00	00.0	01	02.5	02	05.0	
	18.1-23.0	00	00.0	00	00.0	00	00.0	04	10.0	00	00.0	
	23.1-25.0	00	00.0	00	00.0	00	00.0	09	22.5	03	07.5	
	25.1-30.0	00	00.0	00	00.0	00	00.0	12	30.0	09	22.5	
2	**History of previous surgeries**											χ^2 =4.574 df=2 p= 5.99 N.S
	Minor	00	00.0	00	00.0	00	00.0	06	15.0	03	07.5	
	Major	00	00.0	00	00.0	00	00.0	03	07.5	01	02.5	
	Nil	00	00.0	00	00.0	00	00.0	17	42.5	10	25.0	
3	**Nature of cardiac surgery undergone**											χ^2 =1.059 df=3 p= 7.82 N.S
	Coronary Artery Bypass Graft- On Pump	00	00.0	00	00.0	00	00.0	08	20.0	06	15.0	
	Coronary Artery Bypass - Off Pump	00	00.0	00	00.0	00	00.0	06	15.0	03	07.5	
	Valve repair surgery	00	00.0	00	00.0	00	00.0	05	12.5	03	07.5	
	Valve replacement surgery	00	00.0	00	00.0	00	00.0	07	17.5	02	05.0	
4	**Total number of chest tubes**											χ^2 =2.419 df=2 p= 5.99 N.S
	Two	00	00.0	00	00.0	00	00.0	11	27.5	08	20.0	
	Three	00	00.0	00	00.0	00	00.0	13	32.5	06	15.0	
	Four	00	00.0	00	00.0	00	00.0	02	05.0	00	00.0	
5	**Size of chest tube**											χ^2 =1.758 df=2 p= 5.99 N.S
	28 F	00	00.0	00	00.0	00	00.0	11	27.5	03	07.5	
	32 F	00	00.0	00	00.0	00	00.0	12	30.0	09	22.5	
	34 F	00	00.0	00	00.0	00	00.0	03	07.5	02	05.0	
6	**Indwell time of chest tubes**											**χ^2 =8.059 df=3 p= 7.82* S**
	Less than 24 hours	00	00.0	00	00.0	00	00.0	15	37.5	03	07.5	
	24-36 hours	00	00.0	00	00.0	00	00.0	09	22.5	04	10.0	
	37-48 hours	00	00.0	00	00.0	00	00.0	02	05.0	04	10.0	
	More than 48 hours	00	00.0	00	00.0	00	00.0	00	00.0	03	07.5	

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The table 4.10 shows the association of selected clinical variables with the post test I level of pain distress among the cardiac postoperative patients in the experimental group.

The findings revealed that a statistically significant association was found between the post test I levels of pain distress and the clinical variable Indwell time of chest tube **($\chi^2 = 8.059$ at $p = 0.05$)** and no statistically significant association was found between the post test I levels of pain distress and the other clinical variables such as BMI, nature of cardiac surgery undergone, history of previous surgeries, total number of chest tube and size of chest tube.

Findings concluded that samples with less than 24 hours of indwell time of chest tubes had less pain distress than with those, whose indwell was more than 24 hours; hence early the chest tube removal better was the level of pain distress.

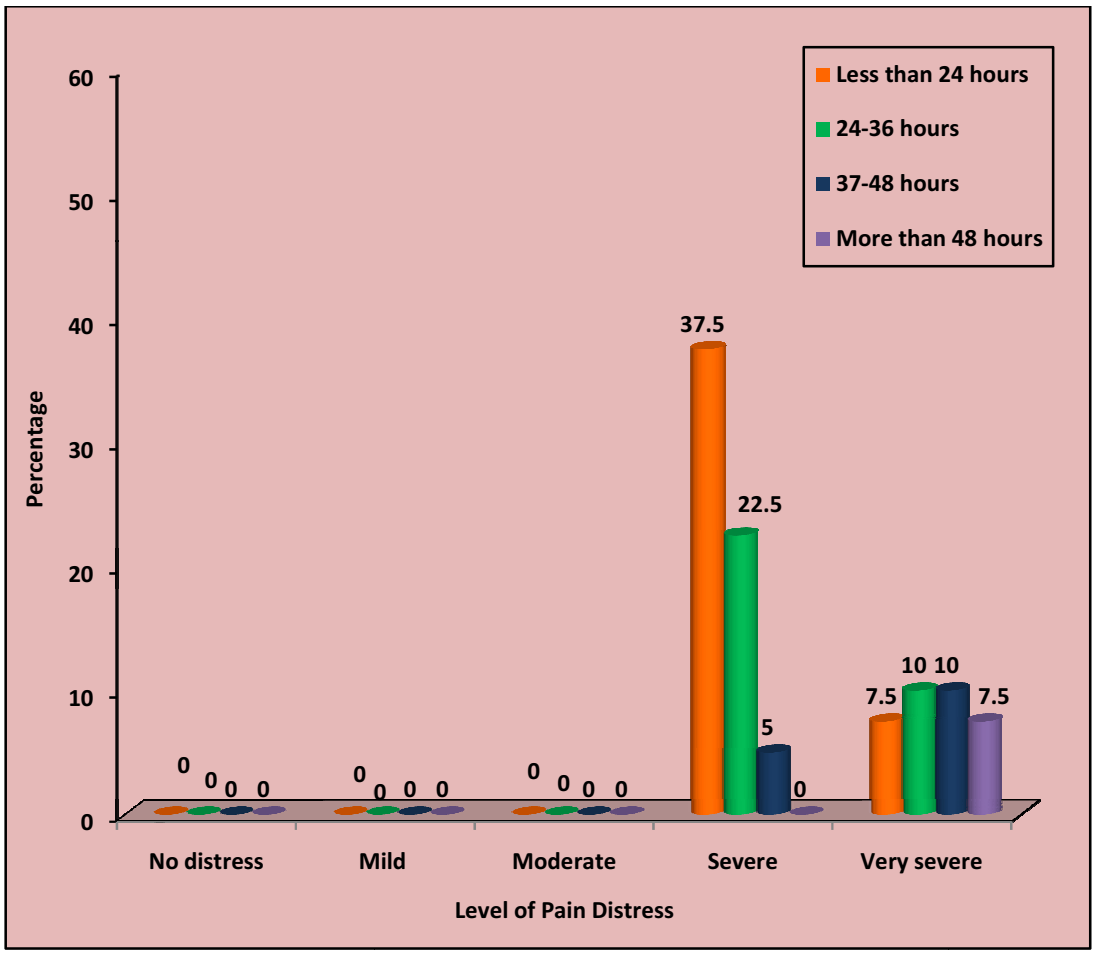

Fig. 4.7: Association of indwell time of chest tubes with the post test I pain distress levels in the experimental group.

Table 4.11: Association of selected demographic variables with the post test II pain distress levels in the experimental group.

N= 40

S. No	Demographic Variables	No Distress		Mild Distress		Moderate Distress		Severe Distress		Very Severe Distress		Chi-Square Value
		n	%	n	%	n	%	n	%	n	%	
1	**Age in years**											
	20-30 years	00	00.0	04	10.0	00	00.0	00	00.0	00	00.0	χ^2 =2.004
	31-40 years	00	00.0	03	07.5	00	00.0	00	00.0	00	00.0	df=4
	41-50 years	00	00.0	07	17.5	02	05.0	00	00.0	00	00.0	p= 9.49
	51-60 years	00	00.0	12	30.0	03	07.5	00	00.0	00	00.0	N.S
	61-70 years	00	00.0	08	20.0	01	05.0	00	00.0	00	00.0	
2	**Gender**											χ^2 =0.261
	Male	00	00.0	26	65.0	04	10.0	00	00.0	00	00.0	df=1
	Female	00	00.0	08	20.0	02	05.0	00	00.0	00	00.0	p= 3.84
												N.S
3	**Education**											
	No formal education	00	00.0	03	07.5	00	00.0	00	00.0	00	00.0	χ^2 =5.839
	Primary school	00	00.0	03	07.5	02	05.0	00	00.0	00	00.0	df=4
	High school	00	00.0	07	17.5	02	05.0	00	00.0	00	00.0	p= 9.49
	Higher Secondary	00	00.0	08	20.0	02	05.0	00	00.0	00	00.0	N.S
	Graduate and above	00	00.0	13	32.5	00	00.0	00	00.0	00	00.0	
4	**Occupation**											
	Professional	00	00.0	16	40.0	03	07.5	00	00.0	00	00.0	χ^2 =2.445
	Skilled worker	00	00.0	08	20.0	00	00.0	00	00.0	00	00.0	df=3
	Unemployed	00	00.0	05	12.5	01	02.5	00	00.0	00	00.0	p= 7.82
	Retired	00	00.0	05	12.5	02	05.0	00	00.0	00	00.0	N.S

***Significant at p=0.05, N.S - Not Significant**

The table 4.11 shows the association of selected demographic variables with the post test II level of pain distress among the cardiac postoperative patients in the experimental group.

The findings revealed that there was no statistically significant association was found between the post test II levels of pain distress and the demographic variables such as age, gender, education and occupation.

Table 4.12: Association of selected clinical variables with the post test II pain distress levels in the experimental group. N= 40

S. No	Clinical Variables	No Distress		Mild Distress		Moderate Distress		Severe Distress		Very Severe Distress		Chi-Square Value
		n	%	n	%	n	%	n	%	n	%	
1	**Body Mass Index**											χ^2 =1.531 df=3 p= 7.82 N.S
	18 and less	00	00.0	03	07.5	00	00.0	00	00.0	00	00.0	
	18.1-23.0	00	00.0	03	07.5	01	02.5	00	00.0	00	00.0	
	23.1-25.0	00	00.0	11	27.5	01	02.5	00	00.0	00	00.0	
	25.1-30.0	00	00.0	17	42.5	04	10.0	00	00.0	00	00.0	
2	**History of previous surgeries**											χ^2 =3.531 df=2 p= 5.99 N.S
	Minor	00	00.0	06	15.0	03	07.5	00	00.0	00	00.0	
	Major	00	00.0	03	07.5	01	02.5	00	00.0	00	00.0	
	Nil	00	00.0	25	62.5	02	05.0	00	00.0	00	00.0	
3	**Nature of cardiac surgery undergone**											χ^2 =2.154 df=3 p= 7.82 N.S
	Coronary Artery Bypass Graft- On Pump	00	00.0	12	30.0	02	05.0	00	00.0	00	00.0	
	Coronary Artery Bypass - Off Pump	00	00.0	07	17.5	02	05.0	00	00.0	00	00.0	
	Valve repair surgery	00	00.0	08	20.0	00	00.0	00	00.0	00	00.0	
	Valve replacement surgery	00	00.0	07	17.5	02	05.0	00	00.0	00	00.0	
4	**Total number of chest tubes**											χ^2 =0.578 df=2 p= 5.99 N.S
	Two	00	00.0	16	40.0	03	07.5	00	00.0	00	00.0	
	Three	00	00.0	16	40.0	03	07.5	00	00.0	00	00.0	
	Four	00	00.0	02	05.0	00	00.0	00	00.0	00	00.0	
5	**Size of chest tube**											χ^2 =2.838 df=2 p= 5.99 N.S
	28 F	00	00.0	13	32.5	01	02.5	00	00.0	00	00.0	
	32 F	00	00.0	16	40.0	05	12.5	00	00.0	00	00.0	
	34 F	00	00.0	05	12.5	00	00.0	00	00.0	00	00.0	
6	**Indwell time of chest tubes**											χ^2 =3.578 df=3 p= 7.82 N.S
	Less than 24 hours	00	00.0	16	40.0	02	05.0	00	00.0	00	00.0	
	24-36 hours	00	00.0	12	30.0	01	02.5	00	00.0	00	00.0	
	37-48 hours	00	00.0	04	10.0	02	05.0	00	00.0	00	00.0	
	More than 48 hours	00	00.0	02	05.0	01	02.5	00	00.0	00	00.0	

***Significant at p=0.05, N.S - Not Significant**

The table 4.12 shows the association of selected clinical variables with the post test II level of pain distress among the cardiac postoperative patients in the experimental group.

The findings revealed that there was no statistically significant association found between the post test II levels of pain distress and the clinical variables such as BMI, nature of cardiac surgery undergone, history of previous surgeries, total number of chest tube, size of chest tube and indwell time of chest tube.

Table 4.13: Association of selected demographic variables with the post test I pain intensity levels in the experimental group. N= 40

S. No	Demographic Variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-Square Value
		n	%	n	%	n	%	n	%	
1	**Age in years**									χ^2 =3.533 df=4 p= 9.49 N.S
	20-30 years	00	00.0	00	00.0	00	00.0	04	10.0	
	31-40 years	00	00.0	00	00.0	00	00.0	03	07.5	
	41-50 years	00	00.0	00	00.0	01	02.5	08	20.0	
	51-60 years	00	00.0	00	00.0	00	00.0	15	37.5	
	61-70 years	00	00.0	00	00.0	00	00.0	09	22.5	
2	**Gender**									χ^2 =3.077 df=1 p= 3.84 N.S
	Male	00	00.0	00	00.0	00	00.0	30	75.0	
	Female	00	00.0	00	00.0	01	02.5	09	22.5	
3	**Education**									χ^2 =7.179 df=4 p= 9.49 N.S
	No formal education	00	00.0	00	00.0	00	00.0	03	07.5	
	Primary school	00	00.0	00	00.0	01	02.5	04	10.0	
	High school	00	00.0	00	00.0	00	00.0	09	22.5	
	Higher Secondary	00	00.0	00	00.0	00	00.0	10	25.0	
	Graduate and above	00	00.0	00	00.0	00	00.0	13	32.5	
4	**Occupation**									χ^2 =5.812 df=3 p= 7.82 N.S
	Professional	00	00.0	00	00.0	00	00.0	19	47.5	
	Skilled worker	00	00.0	00	00.0	00	00.0	08	20.0	
	Unemployed	00	00.0	00	00.0	01	02.5	05	12.5	
	Retired	00	00.0	00	00.0	00	00.0	07	17.5	

***Significant at p=0.05, N.S - Not Significant**

The table 4.13 shows the association of selected demographic variables with the post test I level of pain intensity among the cardiac postoperative patients in the experimental group.

No statistically significant association was found between the post test I level of pain intensity and demographic variables such as age, gender, education and occupation.

Table 4.14: Association of selected clinical variables with the post test I pain intensity levels in the experimental group. N= 40

S. No	Clinical Variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-Square Value
		n	%	n	%	n	%	n	%	
1	**Body Mass Index**									**χ^2 =9.231**
	18 and less	00	00.0	00	00.0	00	00.0	03	07.5	**df=3**
	18.1-23.0	00	00.0	00	00.0	01	02.5	03	07.5	**p= 7.82***
	23.1-25.0	00	00.0	00	00.0	00	00.0	12	30.0	**S**
	25.1-30.0	00	00.0	00	00.0	00	00.0	21	52.5	
2	**History of previous surgeries**									χ^2 =2.231
	Minor	00	00.0	00	00.0	00	00.0	09	22.5	df=2
	Major	00	00.0	00	00.0	00	00.0	04	10.0	p= 5.99
	Nil	00	00.0	00	00.0	01	02.5	26	65.0	N.S
3	**Nature of cardiac surgery undergone**									
	Coronary Artery Bypass Graft- On Pump	00	00.0	00	00.0	00	00.0	14	35.0	χ^2 =3.553
	Coronary Artery Bypass - Off Pump	00	00.0	00	00.0	00	00.0	09	22.5	df=3
	Valve repair surgery	00	00.0	00	00.0	00	00.0	08	20.0	p= 7.82
	Valve replacement surgery	00	00.0	00	00.0	01	02.5	08	20.0	N.S
4	**Total number of chest tubes**									χ^2 =1.254
	Two	00	00.0	00	00.0	01	02.5	18	45.0	df=2
	Three	00	00.0	00	00.0	00	00.0	19	47.5	p= 5.99
	Four	00	00.0	00	00.0	00	00.0	02	05.0	N.S
5	**Size of chest tube**									χ^2 =1.905
	28 F	00	00.0	00	00.0	01	02.5	13	27.5	df=2
	32 F	00	00.0	00	00.0	00	00.0	21	52.5	p= 5.99
	34 F	00	00.0	00	00.0	00	00.0	05	12.5	N.S
6	**Indwell time of chest tubes**									**χ^2 =8.553**
	Less than 24 hours	00	00.0	00	00.0	00	00.0	18	45.0	**df=3**
	24-36 hours	00	00.0	00	00.0	00	00.0	13	27.5	**p= 7.82***
	37-48 hours	00	00.0	00	00.0	00	00.0	06	15.0	**S**
	More than 48 hours	00	00.0	00	00.0	01	02.5	02	05.0	

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The table 4.14 shows the association of selected clinical variables with the post test I level of pain intensity among the cardiac postoperative patients in the experimental group.

The findings revealed that a statistically significant association was found between the post test I level of pain intensity and the clinical variable BMI (**χ^2 = 9.231 at p = 0.05 level)** and indwell time of chest tube (**χ^2 = 9.231 at p = 0.05 level).** No statistically significant association was found with the other clinical variables such as nature of cardiac surgery undergone, history of previous surgeries, total number of chest tube and size of chest tube.

Findings concluded that samples with increased BMI had experienced severe intensity of pain than with those whose BMI was less. It also revealed that more the indwell time of the chest tubes more the intensity of pain, hence early the chest tube removal better was the intensity of pain.

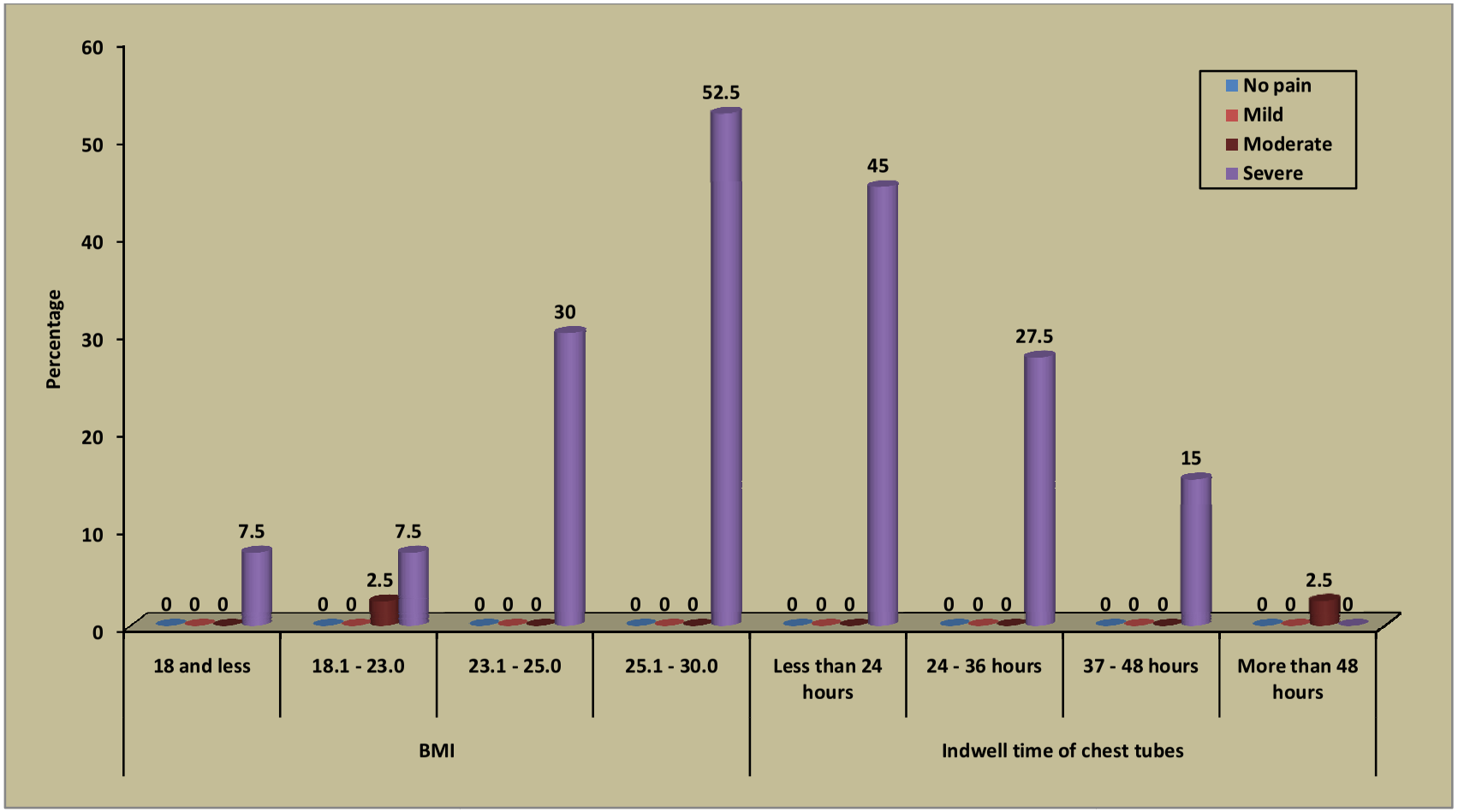

Fig.4.8: Association of BMI and Indwell time of chest tubes with the post test I pain intensity levels in the experimental group.

Table 4.15: Association of selected demographic variables with the Post test II pain intensity levels in the experimental group. N= 40

S. No	Demographic Variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-Square Value
		n	%	n	%	n	%	n	%	
1	**Age in years**									
	20-30 years	00	00.0	02	05.0	02	05.0	00	00.0	χ^2 =4.889
	31-40 years	00	00.0	01	02.5	02	05.0	00	00.0	df=4
	41-50 years	00	00.0	07	17.5	02	05.0	00	00.0	p= 9.49
	51-60 years	00	00.0	05	12.5	10	25.0	00	00.0	N.S
	61-70 years	00	00.0	05	12.5	04	10.0	00	00.0	
2	**Gender**									**χ^2 =4.880 df=1 p= 3.84* S**
	Male	00	00.0	12	30.0	18	45.0	00	00.0	
	Female	00	00.0	08	20.0	02	05.0	00	00.0	
3	**Education**									
	No formal education	00	00.0	01	02.5	02	05.0	00	00.0	
	Primary school	00	00.0	04	10.0	01	02.5	00	00.0	χ^2 =4.568
	High school	00	00.0	05	12.5	04	10.0	00	00.0	df=4
	Higher Secondary	00	00.0	06	15.0	04	10.0	00	00.0	p= 9.49
	Graduate and above	00	00.0	04	10.0	09	22.5	00	00.0	N.S
4	**Occupation**									
	Professional	00	00.0	07	17.5	12	30.0	00	00.0	χ^2 =7.268
	Skilled worker	00	00.0	06	15.0	02	05.0	00	00.0	df=3
	Unemployed	00	00.0	05	12.5	01	02.5	00	00.0	p= 7.82
	Retired	00	00.0	02	05.0	05	12.5	00	00.0	N.S

***Significant at p=0.05, N.S - Not Significant, S - Significant**

The table 4.15 shows the association of selected demographic variables with the post test II intensity of pain levels among the cardiac postoperative patients in the experimental group.

The findings revealed that a statistically significant association was found between the post test II intensity of pain and the demographic variable gender (**χ^2 = 4.800 at p = 0.05 level**) and no statistically significant association was found with the other demographic variables such as age, education and occupation.

Findings concluded that male patients had experienced more intensity of pain (moderate pain intensity) than female patients.

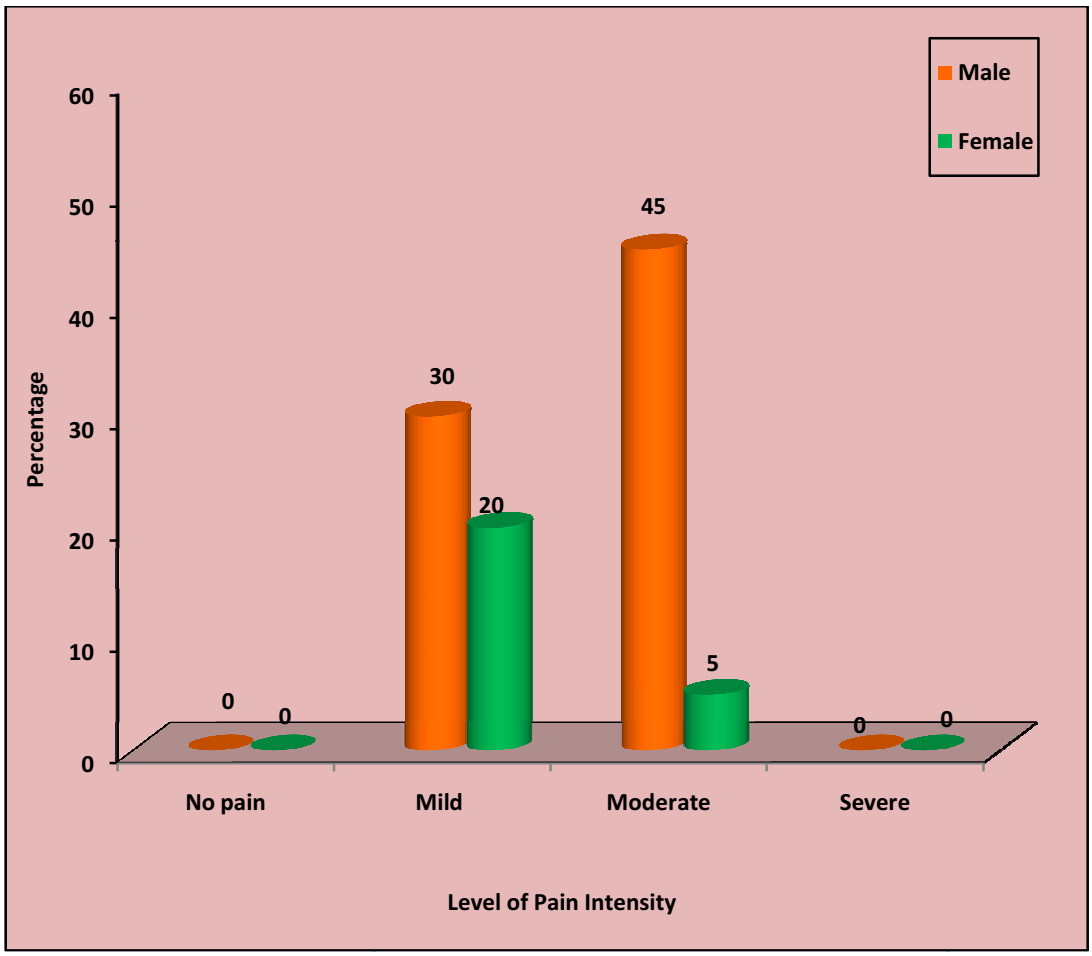

Fig. 4.9: Association of gender with the post test II pain intensity levels in the experimental group.

Table 4.16: Association of selected clinical variables with the post test II pain intensity levels in the experimental group. N= 40

S. No	Clinical Variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-Square Value
		n	%	n	%	n	%	n	%	
1	**Body Mass Index**									χ^2 =4.762 df=3 p= 7.82 N.S
	18 and less	00	00.0	01	02.5	02	02.5	00	00.0	
	18.1-23.0	00	00.0	04	10.0	00	00.0	00	00.0	
	23.1-25.0	00	00.0	06	15.0	06	15.0	00	00.0	
	25.1-30.0	00	00.0	09	22.5	12	30.0	00	00.0	
2	**History of previous surgeries**									χ^2 =3.053 df=2 p= 5.99 N.S
	Minor	00	00.0	05	12.5	05	12.5	00	00.0	
	Major	00	00.0	03	07.5	01	02.5	00	00.0	
	Nil	00	00.0	12	30.0	14	35.0	00	00.0	
3	**Nature of cardiac surgery undergone**									χ^2 =1.897 df=3 p= 7.82 N.S
	Coronary Artery Bypass Graft- On Pump	00	00.0	06	15.0	08	20.0	00	00.0	
	Coronary Artery Bypass - Off Pump	00	00.0	06	15.0	03	07.5	00	00.0	
	Valve repair surgery	00	00.0	03	07.5	05	12.5	00	00.0	
	Valve replacement surgery	00	00.0	05	12.5	04	10.0	00	00.0	
4	**Total number of chest tubes**									χ^2 =1.053 df=2 p= 5.99 N.S
	Two	00	00.0	10	25.0	09	22.5	00	00.0	
	Three	00	00.0	09	22.5	10	25.0	00	00.0	
	Four	00	00.0	01	02.5	01	02.5	00	00.0	
5	**Size of chest tube**									χ^2 =0.248 df=2 p= 5.99 N.S
	28 F	00	00.0	07	17.5	07	17.5	00	00.0	
	32 F	00	00.0	11	27.5	10	25.0	00	00.0	
	34 F	00	00.0	02	05.0	03	07.5	00	00.0	
6	**Indwell time of chest tubes**									χ^2 =2.762 df=3 p= 7.82 N.S
	Less than 24 hours	00	00.0	09	22.5	09	22.5	00	00.0	
	24-36 hours	00	00.0	08	20.0	05	12.5	00	00.0	
	37-48 hours	00	00.0	02	05.0	04	10.0	00	00.0	
	More than 48 hours	00	00.0	01	02.5	02	05.0	00	00.0	

***Significant at p=0.05, N.S - Not Significant, S – Significant**

The table 4.16 shows the association of the clinical variables with the post test II intensity of pain among the cardiac postoperative patients in the experimental group.

The findings revealed that there was no statistically significant association found between the post test II intensity of pain and the clinical variables such as BMI, nature of cardiac surgery undergone, history of previous surgeries, total number of chest tube, size of chest tube and indwell time of chest tube.

DISCUSSION

CHAPTER – 5

DISCUSSION

This chapter deals with the detailed discussion on the findings of the study interpreted by statistical analysis. The findings are discussed in relation to the objectives, need for the study, related literature and conceptual framework.

The present study was executed to assess the effectiveness of cryotherapy on procedural pain among cardiac post operative patients. The findings of the study proved that there was a significant reduction in the procedural pain after the application of cryotherapy. The findings are discussed objective wise and presented below:

Description of demographic variables

The selected demographic variables of the study were age, gender, educational qualification and occupation. With regard to age 15(37.5%) of them were in 51-60 yrs age group in experimental group and 13(32.5%) of them were in 41-50 yrs age group in control group. Considering the gender 30(75%) samples in the experimental group and 27(67.5%) in the control group were males.

Considering education, 13(32.5%) of them were graduate and above and only 3 (7.5%) of them had no formal education in the experimental group. Correspondingly in the control group 11(24.5%) of them had completed high school and higher secondary education and 3 (7.5%) of them had no formal education. When considering the occupation 19(47.5%) of them were professionals and only 6(15%) of them were unemployed in the experimental group. Likewise in the control group 16(40%) of them were professionals and 6(15%) of them were retired.

The findings concluded that a majority of the samples in the study were males between the age group of 51-60 years and most of them were professionals with an educational qualification of graduate and above.

Description of clinical variables

Regarding Body Mass Index 21(52.5%) patients in experimental group and 19(47.5%) in control group were having BMI in the range of (25.1 -30); of which 3(7.5%) of them in the experimental and 2(5%) of them in control group had BMI less than 18. Taking the variable history of surgery a maximum of the samples 27(67.5%) in experimental and 25(62.5%) in control group had no surgery undergone while 9(22.5%) and 12(30%) of them had undergone minor surgery in experimental and control group respectively. Major surgeries were undergone by 4(10%) patients in experimental group and 3(7.5%) patients in control group.

With view to the nature of cardiac surgery undergone, 14(35%) of them in the experimental group and 17(42.5%) of them in control group had undergone Coronary Artery Bypass Graft- On Pump. Similarly 9(22.5%) in the experimental group and 6(15%) of them in control group had undergone Coronary Artery Bypass - Off Pump. 8 (20%) of the cardiac postoperative patients in the experimental group and 7(17.5%) in control group had undergone Valve repair surgery. Valve replacement surgery was undergone by 8(20%) and 7(17.5%) patients in experimental and control group respectively.

When considering the total number of chest tubes, 19(47.5%) of them had two as well as three chest tubes in the experimental group. While 16(40%) of them had two chest tubes and 20(50%) of them had three chest tubes in control group. Regarding size of the chest tube 21(52.5%) of them in the experimental and 17(42.5%) in the control group had 32F while 5(12.5%) of the samples in the experimental group and 3(7.5%) of them in the control group had chest tube of 32F.

Concerning the indwell period of chest tube about 18(45%) patients in experimental group and 14(35%) in control group had indwell period less than 24 hours; 13(32.5%) of them had chest tube for 24-36 hours in experimental group and 16(40%) in the control group had chest tube for 24-36 hours. About 6(15%) patients in experimental and 8(20%) patients in control group were having the chest tubes for 37-48 hours. While 3(7.5%) of the patients in the experimental group and 2(5%) of them in control group had indwell time of chest tube for more than 48 hours.

The study findings revealed that majority of the samples were having BMI of (25.1-30.0) with history of no previous surgeries. Most of the samples had undergone CABG with most of them having two or three chest tubes of either 28F or 32F for duration of 36 hours of indwell.

The first objective was to assess the baseline and post test level of procedural pain in experimental and control group.

When taking into account the baseline level of pain distress in the experimental group, 10(25%) of them had mild pain distress and 30(75%) of them had moderate pain distress with mean score of 18.10 and S.D of 2.023. Whereas in control group 5(12.5%) of them had mild pain distress and 35(87.5%) of them had moderate pain distress with mean score of 18.30 and S.D of 1.572. The post test I level of pain distress in the experimental group showed that 26(65%) of them had severe pain distress and 14(40%) of them had very severe pain distress with mean score of pain distress of 31.65 and S.D of 2.607; whereas all 40(100%) of them in the control group had very severe pain distress with the mean score of pain distress of 35.03 and S.D of 1.209. The post test II level of pain distress showed that 34(85%) and 6(15%) of them in the experimental group had mild and moderate pain distress level respectively with mean score of 14.90 and S.D of 1.892. But in control group 14(35%) and 26(65%) of them had mild and moderate pain distress level respectively with mean score of 17.78 and S.D of 1.928.

The findings indicated that there was no significant difference in the baseline level of pain distress between the experimental group and the control group. Hence making it obvious from the above data that the cardiac post operative patients both in experimental and control group had certain amount of pain distress even before the chest tube removal which was measured as baseline pain distress level. The post test I findings revealed that samples from both the experimental and control group experienced very severe pain distress but there was significant difference between both of them showcasing the effect of cryotherapy(cooling gel pack). In the post test II the pain distress had comparatively reduced in both the experimental and control group but a significant difference was noted between the experimental group and the control group indicating sustained effect of the cooling gel pack on the level of procedural pain distress.

Considering the baseline level of pain intensity in the experimental group 13(32.5%) of them had mild pain and 27(67.5%) of them had moderate pain with baseline mean score of 48.55 and S.D of 7.056. Whereas in control group 12(30%) had mild pain and 28(70%) of them had moderate pain with baseline mean score of pain intensity of 48.38 and S.D of 7.379. While assessing the post test I level of pain intensity 1(2.5%) of them had moderate pain and 39(97.5%) of them had severe pain in the experimental group with mean score of 84.90 and S.D of 4.744; whereas all 40(100%) of them had severe pain in the control group with mean score of pain intensity of 89.45 and S.D 3.796. The post test II level of pain intensity revealed that 20(50%) samples in the experimental group had mild pain intensity and 20(50%) of them had moderate pain intensity with mean score of 44.75 and S.D of 7.037; while 5(12.5%) of them had mild pain intensity and 35(87.5%) of them had moderate pain intensity with mean score of 51.73 and S.D of 6.496 in the control group.

The present study findings makes it comprehensible that the cardiac post operative patients both in experimental and control group had certain amount of pain even before the chest tube removal which was measured as baseline pain level and there was no statistically significant difference in the level of pain intensity between the experimental and the control group. The findings of the post test I revealed that the samples from both the experimental and control group experienced severe pain intensity with no significant difference between both of them. In the post test II the pain intensity had comparatively reduced in both the experimental and control group but with a significant difference was noted between the two groups that indicated the sustained effect of the cooling gel pack on the procedural pain intensity level.

The results of the study was reliable with the study findings of that conducted by **Nurcan Ertug (2011**) who evaluated the effect of cold application on pain due to chest tube removal by carrying out an experimental study among 140 patients with 70 each in the experimental and control group at Thoracic hospital, Turkey. The study group received cold application prior to chest tube removal and pain intensity was assessed in both groups using visual analogue scale. The findings showed that there was a significant difference in pain with cold application between the two groups. The results confirmed that cold application was effective in reducing the pain due to chest tube removal.

The second objective was to assess the effectiveness of cryotherapy on the level of procedural pain in the experimental and control group.

Taking an account of the procedural pain distress levels, the baseline pain distress in the experimental group had a mean score of 18.10 and SD of 2.023 whereas the control group had the mean score of 18.30 with SD of 1.572. With regard to the post test I pain distress, the mean score was 31.65 with SD of 2.607 in the experimental group and in the control group the mean score was 35.03 with SD of 1.209. With respect to the post test II pain distress, the mean score was 14.90 with SD of 1.892 in the experimental group and in the control group the mean score was 17.78 with SD of 1.928.

No statistically significant difference in the base line pain distress between the experimental and the control group was found using the student unpaired‘t’ test therefore which revealed the homogeneity of the samples. The students unpaired ‘t’ test also revealed that there is statistically significant difference between the experimental group and control group in post test I **(t= 7.428 at p=0.05 level)** which proved that cryotherapy had significant impact on reducing the procedural pain distress level among the cardiac postoperative patients. There is a statistically significant difference between the experimental group and control group in post test II level of pain distress using the student unpaired ‘t’ test which **(t= 6.731 at p=0.05 level)** proved that cryotherapy had a sustained effect and significant impact on reducing the procedural pain distress level among the cardiac postoperative patients.

The study findings revealed that cryotherapy had immediate and sustained effect on reducing the level of procedural pain distress among the cardiac postoperative patients.

Considering the procedural pain intensity level, the baseline pain intensity of the experimental group had a mean score of 48.55 with SD of 7.056 and in the control group the mean score was 48.38 with SD of 7.379. With regard to the post test I pain intensity, the mean score was 84.90 with SD of 4.744 in the experimental group and in the control group the mean score was 89.45 with SD of 3.796. With respect to the post test II pain intensity, the mean score was 44.75 with SD of 7.037 in the experimental group and in the control group the mean score was 51.73 with SD of 6.496.

There was no statistically significant difference in the base line level of pain intensity between the experimental and the control group using the student unpaired 't' test which revealed the homogeneity of the samples. The above test also revealed that there was statistically significant difference between the experimental group and control group in post test **I (t= 4.737 at p=0.05 level)** which proved that cryotherapy had significant impact on reducing the procedural pain intensity among the cardiac postoperative patients. A statistically significant difference was observed between the experimental group and control group in the post test II level of pain intensity using unpaired 't' test **(t= 4.606 at p=0.05 level)** which proved that cryotherapy had sustained significant effect and impact on reducing the procedural pain intensity among the cardiac postoperative patients.

The study findings revealed that cryotherapy had immediate and sustained effect on reducing the level of procedural pain intensity among the cardiac postoperative patients.

Therefore, the hypothesis NH_1 which was stated earlier that **"There is no significant difference in the post test level of procedural pain among the cardiac post operative patients between the experimental and control group at p<0.05"**was not accepted.

The findings were significant with the study conducted by **Yurdanur Demir et al (2010)** who carried out single randomized experimental study to assess the effectiveness of cold application in combination with standard analgesic administration on pain and anxiety during chest tube removal among 90 patients with Body Mass Index less than 30, who were divided into 3 groups cold application group, warm application group, group without application. The intensity of pain was measured using visual analogue scale. The findings revealed that the reduction in pain intensity associated with chest tube removal on application of cold was found to be statistically significant with a moderate level of pain (6.77 + or – 2.33). The study findings revealed that application of cold packs would reduced the intensity of pain during CTR but had no effect on reducing the anxiety levels or pain quality associated with CTR. The study suggested that cold application can be used for pain management during chest tube removal.

The third objective was to associate post test level of procedural pain with selected demographic and clinical variables of experimental group.

The level of procedural pain(pain distress and pain intensity) was associated with selected demographic and clinical variables of the experimental group such as age, gender, education, occupation, BMI, nature of cardiac surgery, history of previous surgery, total number of chest tubes, size of chest tube and indwell time of chest tube by using Chi-square test. The association of the post test I level of pain distress with selected demographic and clinical variables of experimental group revealed that there was a statistically significant association for the clinical variable indwell time of chest tube (**χ^2=8.059 at p<0.05 level**) and other variables such as age, gender, educational qualification, occupation, BMI, history of previous surgery undergone and size of chest tubes, showed to have no statistically significant association.

The association of the post test II level of pain distress with selected demographic and clinical variables of the experimental group revealed that there was no statistically significant association.

The association of the level of post test I level of pain intensity with selected demographic and clinical variables of the experimental group revealed that the clinical variable BMI (**χ^2=9.231 at p<0.05 level**) and indwell time of chest tube (**χ^2=8.533 at p<0.05 level)** showed to have statistically significant association and other variables such as age, gender, educational qualification, occupation, history of previous surgery undergone and size of chest tubes, showed to have no statistically significant association.

The association of the post test II level of pain intensity with selected demographic and clinical variables of the experimental group revealed that for gender (**χ^2=4.800 at p<0.05 level)** showed to have had statistically significant association and other variables such as age, educational qualification, occupation, history of previous surgery undergone, size of chest tubes, BMI and indwell tie of chest tube showed to have no statistically significant association.

Hence the hypothesis NH_2 which stated earlier that **"There is no significant association of level of procedural pain with selected demographic and clinical**

variables of experimental group at p<0.05" was not accepted for the demographic variable gender and clinical variables, indwell time of the chest tube and BMI. It was accepted for other demographic and clinical variables.

The findings of the study was supported by the study of **Mohsen Mohammed (2010)** who conducted a prospective study to assess the impact of chest tube indwell time following CABG among 307 patients who were randomly assigned to two groups at Isfahan University, Iran. In group one chest tubes were removed within 24 hours after surgery whereas in group two the chest tubes where removed in the second 24 hours after surgery. Respiratory rate and pain levels were assessed. The findings revealed that the pain level evaluated at 24 hours post operatively was lower in the first group and the difference in the pain level between the second group evaluated at 30 hours postoperatively was significant (P=0.016). The study concluded that early extracting of chest tubes after coronary artery bypass graft surgery when there is no significant drainage can lead to pain reduction and consuming oxygen which is an effective measure after surgery towards healing.

SUMMARY,

CONCLUSION,

IMPLICATIONS,

RECOMMENDATIONS

AND LIMITATIONS

CHAPTER – 6

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

The present study was aimed to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients. This chapter deals with summary, conclusion, implications, recommendations and limitations.

6.1 SUMMARY

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Acute pain is common after cardiac surgery. Pain can significantly interfere with the persons quality of life and general functioning. Pain during chest tube removal after cardiac surgery is poorly controlled despite analgesics, the therapeutic effects of cryotherapy (cooling gel pack) decreases the nerve conduction velocity and pain intensity. Hence the investigator undertook the present study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative clients at selected setting, Chennai.

The objectives of the study were

1. To assess the baseline and post test level of procedural pain in experimental and control group.
2. To assess the effectiveness of cryotherapy on the level of procedural pain in the experimental and control group.
3. To associate post test level of procedural pain with selected demographic and clinical variables of experimental group.

The study was based on the assumptions that

1. Chest tube removal causes severe agonizing pain for the patient's inspite of the routine analgesics being administered.
2. The patients undergoing chest tube removal need additional therapies to manage their pain along with the routine analgesics.
3. Ice application has an effect in reducing any pain.

The Null hypotheses formulated were

NH_1 : There is no significant difference in the post test level of procedural pain among the cardiac post operative patients between the experimental and control group at $p<0.05$.

NH_2: There is no significant association of level of procedural pain with selected demographic and clinical variables of the experimental group at $p<0.05$.

The broad review of related literature, professional experience and experts guidance which provided the strong foundation for the study including the basis for the conceptual framework and formation of the tool.

The conceptual framework for this study was developed based on Wiedenbach's Helping art of clinical nursing theory, which provided the comprehensive framework for evaluating the effectiveness of ice pack application.

The research methodology of the study was:

The research design used in this study was true experimental post test only design and it was conducted in the post operative cardiac AICU of Madras Medical Mission hospital, Chennai. The content validity of the tool was obtained from 5 experts and reliability of the tool was done by inter-rater method. The pilot study was conducted in the post operative cardiac ICU- III of the Madras Medical Mission hospital, Chennai. For the main study 80 samples were selected by using simple random sampling technique using lottery method in which 40 was allotted to the experimental group and 40 to the control group. The experimental group had the cryotherapy (cooling gel pack) being applied around the chest tube insertion site for 15 minutes before chest tube removal along with hospital routine (Inj.Perfelgan) 30minutes before the chest tube removal whereas in the control group, the patients were administered only the usual hospital routine before chest tube removal. The data was collected by using modified comfort scale (pain distress) and visual analogue scale (pain intensity) 30 minutes before Chest Tube Removal (CTR), during CTR within 5minutes and 20 minutes after CTR. The data collected was organized and tabulated for analysis.

The major findings of the study were:

The data collected was analyzed using descriptive and inferential statistics. The overall statistical analysis in the experimental group revealed that the post test I level of pain distress 26(65%) of them had severe pain distress and 14(40%) of them had very severe pain distress. The post test II level of pain distress showed that 34(85%) and 6(15%) of them in the experimental group had mild and moderate pain distress level respectively. The posttest I mean score of pain distress of 31.65 with the S.D of 2.607and post test II level of mean score on pain distress was 14.90 with S.D of 1.892.

Whereas the overall statistical analysis in the control group revealed that the post test I level of pain distress 40(100%) of them had very severe pain distress and the post test II level of pain distress showed that 14(35%) patients had mild pain and 26(65%) patients had moderate pain in the experimental group. The posttest I mean score of pain distress was 35.03 with S.D of 1.209 post test II level of mean score on pain distress was 17.78 with the S.D of 1.982.

Taking on the whole, the statistical analysis of the post test I level of pain intensity in the experimental group revealed that 1(2.5%) of the patient had moderate pain intensity and 39(97.5%) of them had very severe pain intensity. The post test II level of pain intensity showed that 20(50%) and 20(50%) of them in the experimental group had mild pain respectively. The posttest I mean score of pain intensity in the experimental group was 84.90 with S.D of 4.744 and the pain intensity in the post test II was found to have a mean score of 44.75 with the S.D of 7.037 in the experimental group.

Whereas the overall statistical analysis in the control group revealed that the post test I level of pain intensity 40(100%) of them had very severe pain intensity and the post test II level of pain intensity showed that 5(12.5%) and 35(87.5%) of them in the experimental group had mild and moderate pain intensity level respectively. The posttest I mean score of pain intensity of 89.45 with the S.D of 3.796 post test II level of mean score on pain intensity was 51.73 with the S.D of 6.496.

The results confirmed that there was statistically significant difference in the level of pain distress between the experimental and control group in post test I

at $p<0.05$ level of significance with a " t" value of 7.428 and for post test II at $p<0.05$ level of significance with a " t" value of 6.731. There was also a statistically significant difference in the level of pain intensity between the experimental and control group in post test I at $p<0.05$ level of significance with a " t" value of 4.737 and for post test II at $p<0.05$ level of significance with a " t" value of 4.606.

Thus, the findings depicted that there was a significant difference i.e. reduction in level of procedural pain after cryotherapy (cooling gel pack) application prior to chest tube removal among cardiac post operative patients in the experimental group.

6.2 CONCLUSION

This study assessed the effectiveness of cryotherapy on the procedural pain among cardiac post operative patients at selected setting, Chennai. The findings verified that cryotherapy was very effective in pain reduction during chest tube removal and thus can be used as a non pharmacological measure to control pain during chest tube removal.

The investigator concluded that cryotherapy (cooling gel pack) can be used as a non pharmacological intervention in reducing pain as it provides a safe and effective reduction in pain without side effects. In the study the cooling gel packs were applied along with hospital routine analgesic (Inj.Perfelgan 100ml) for 15 minutes prior to chest tube removal and it was confirmed that cryotherapy reduced the intensity and distress of pain associated with chest tube removal.

6.3 IMPLICATIONS

Nursing Practice

Pain is the fifth vital sign and the management of pain is a high priority for nursing care. The ICU nurses have a vital role in assessing the post operative level of pain and plan appropriate pharmacological and non pharmacological interventions to relieve pain and prevent post operative complications.

This can be facilitated by motivating the nurses to understand the significance of non pharmacological interventions like ice application which are inexpensive and easily available to minimize the pain intensity and pain distress in post operative patients and

also encourage the staff nurses to follow the intervention protocol during chest tube removal.

Nursing Education

Nurse educators can educate the students about the pain mechanism, assessment methods and various pharmacological and non pharmacological interventions to relieve pain and ensure that the students learn about the significance of post operative pain management, prevention of post operative complications due to pain and the side effects of analgesic medications.

Nurse educator can arrange and conduct workshops, conferences and seminars on pain management and highlight the effectiveness of simple, inexpensive and easily available interventions like ice pack and cooling gel pack application in reduction of pain during painful procedures such as chest tube removal. The nurse educator can encourage the students for effective utilization of research based practice in reducing pain which will help to minimize the requirement of narcotic analgesics.

Nursing Administration

Nurse administrator can collaborate with governing bodies in formulating policies to employ specially qualified nurses in post operative pain management in ICU. The nurse administrator should formulate protocols, policies, guidelines and system of care given by nurses during procedures like chest tube removal. Nurse administrator ensures the implementation of nursing interventions which are research based and clinically effective in promoting the comfort of the patient.

Nursing Research

Nurse researcher can encourage clinical nurse to apply the research findings in their daily nursing care activities and can bring out new innovative techniques used to promote comfort of the patient. Nurse researcher can promote research with regard to utilization of pharmacologic and non pharmacological agents to relieve pain in clinical practice.

Dissemination of the findings through conferences, professional journals will make the application of research findings to be effective. Nurse researcher should be

motivated to conduct more studies to know the therapeutic effects of ice in reducing the discomfort of the patients.

6.4 RECOMMENDATIONS

Based on the study findings, the recommendations are

1. The researcher has recommended the use of cryotherapy in protocol during chest tube removal at the Madras Medical Mission hospital.
2. The study can be conducted for a larger group in different setting for better generalisation of the findings.
3. The modified comfort scale could be incorporated in the hospital for assessing the pain distress levels among the patients.
4. Effectiveness of other non pharmacological interventions like music therapy, guided imagery and relaxation therapy in reduction of pain during chest tube removal could be studied.
5. A comparative study can be done to assess the effectiveness of ice application with other non pharmacological interventions.
6. The effectiveness of cooling gel pack application during the removal of drainage tube following major abdominal surgeries could be studied.

6.5 LIMITATIONS

1. The investigator faced difficulty in collecting the related literature as there were limited studies on the effectiveness of cooling gel pack application in reduction of pain during chest tube removal.

6.6 COMMUNICATION OF FINDINGS

The researcher is planning to communicate the findings either by a paper presentation or to publish the findings in an indexed journal so that the results can be generalized and utilized by all staff nurses working in the cardiac post operative ICU's.

6.7 UTILIZATION OF THE RESEARCH FINDINGS

The findings will be utilized in the cardiac post operative intensive care units of MMM hospital once after the approval of thesis. A protocol will be prepared, consisting of the steps to be followed by the staff nurses during CTR which will include pre-procedural preparation of the patients along with prompt assessment of pain and its

associated symptoms and combination of pharmacological and non pharmacological methods of pain control. The researcher feels that the protocol will thus make CTR less complicated and less distressing for the patients and it will heighten the need for effective post operative pain management among nurses working in ICU.

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APPENDICES

MMM COLLEGE
OF NURSING
Learn to Serve
A Unit of
The Madras Medical Mission

MMMCON/RL/07/2015 **16th February 2015**

To
Dr. Rajan
Director – Cardiac Surgery
Madras Medical Mission
Chennai

Respected Sir,

This is to certify that Ms. Divya T Francis is a bonafide student of MMM College of Nursing and currently undergoing MSc(N) in the branch of Medical Surgical Nursing (Cardio Thoracic Nursing). As part of her Curriculum, she needs to conduct a study in the department of Cardiology for her dissertation. Her problem statement is **"A true experimental study to assess the effectiveness of Cryotherapy on procedure pain among the cardiac post operative patients at a selected setting in Chennai"**

The same was presented before the ethical committee of the MMM Hospital. The committee has advised to get consent from the surgeons individually to do it on their patients. Kindly permit her to do the same.

Kindly do the needful

Thank You

Approved
To go for Ethics committee clearance.

16/2/15

DR. ROSALINE RACHEL, PH.D (N)
PRINCIPAL
MMM COLLEGE OF NURSING

Dr. S. Rajan
Director - Cardiac Surgery
Institute of Cardio - Vascular Diseases
Madras Medical Mission
Chennai - 600 037.

23-4-2015

Dr. V.M. Kumar
23-04-2015

MMM College of Nursing
No. 131, Sakthi Nagar, Nolambur
Mogappair West, Chennai - 600 095
Phone: 044-26535001, 26535002
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Registered Office :
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No. 4A, Dr.J.J.Nagar, Mogappair,
Chennai - 600 037
Phone : 044-26565961, 26565991, 26561801.

MMM COLLEGE
OF NURSING
Learn to Serve
A Unit of
The Madars Medical Mission

MMMCON/RL/11/2015 **23rd April 2015**

To
Dr. Rajan
Director – Cardiac Surgery
Madras Medical Mission
Chennai

Respected Sir,

This is to certify that **Ms. Divya T Francis** is a bonafide student of MMM College of Nursing and currently undergoing MSc(N) in the branch of Medical Surgical Nursing (Cardio Thoracic Nursing). As part of her Curriculum, she needs to conduct a study in the department of Cardiology for her dissertation. Her problem statement is **"A true experimental study to assess the effectiveness of Cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai"**

The same was accepted by the ethical committee of the MMM Hospital. Kindly permit her to do the main study & pilot study.

Kindly do the needful

Thank You

23/4/15

DR. ROSALINE RACHEL, PH.D
PRINCIPAL
MMM COLLEGE OF NURSING

Approved and also by Ethics committee approval
DNI-MMM
23-4-2015

MMM College of Nursing
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MMM COLLEGE
OF NURSING
Learn to Serve
A Unit of
The Madars Medical Mission

MMMCON/RL/16/2015 **25th April 2015**

To
Ms. Sosamma John
Nursing Superintendent
Madras Medical Mission
Chennai

Respected Madam,

This is to certify that **Ms. Divya T Francis** is a bonafide student of MMM College of Nursing and currently undergoing MSc(N) in the branch of Medical Surgical Nursing (Cardio Thoracic Nursing). As part of her Curriculum, she needs to conduct a study in the department of Cardiology for her dissertation. Her problem statement is **"A true experimental study to assess the effectiveness of Cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai"**

The same was accepted by the ethical committee of the MMM Hospital. Kindly permit her to do the main study & pilot study.

Kindly do the needful

Thank You

25/4/15
DR. ROSALINE RACHEL, PH.D
PRINCIPAL
MMM COLLEGE OF NURSING

ok
27/4/15

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INSTITUTIONAL ETHICS COMMITTEE
THE MADRAS MEDICAL MISSION
No. 4-A, Dr. J.J. NAGAR, MOGAPPAIR, CHENNAI - 600 037, INDIA
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E-mail : icvddoctors@mmm.org.in Website : http://www.mmm.org.in

To

Date: 17 Apr 2015

Ms. Divya Thankachan Francis
Madras Medical Mission,
Chennai 600037

EC Reg no: ECR/140/Inst/TN/2013

Ref: Effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai

Sub: Ethics Committee approval of study document for the above mentioned study.

Dear Ms. Divya Thankachan Francis

We have received from you 06+1 copies of each of following study related document submitted vide letter dated: 08 Apr 2015.

1. Protocol Synopsis
2. Assessment Tool

At the Ethics Committee meeting held on 11 Apr 2015 your referenced letter and the above documents were examined and discussed. After due consideration, the committee has decided to approve the above-mentioned document.

The following members were present at the meeting held on 11 Apr 2015 at 9-30 AM at Mount Tabour Lounge, Madras Medical Mission.

Name & Qualification	Primary Scientific or Non scientific Specialty	Affiliation with the institution	Gender
Dr. M.S. Ramachandran, MBBS,MD,FRCP,FICP,DSC(HONS), Prof.Director medicine(Rtd)	Chairperson	No	M
Dr V M Kurian, MS, MCh, DPMR. Sr. Consultant cardiovascular Surgeon Madras Medical Mission	Member secretary	Yes	M

INSTITUTIONAL ETHICS COMMITTEE
THE MADRAS MEDICAL MISSION
No. 4-A, Dr. J.J. NAGAR, MOGAPPAIR, CHENNAI - 600 037, INDIA
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E-mail : icvddoctors@mmm.org.in Website : http://www.mmm.org.in

Dr Ajit Mullasari, MD DNB DM, Director of cardiology, Madras Medical Mission	Member Clinician	Yes	M
Dr J. Ezhilan MD, DM , DNB, FNB Sr. Consultant Cardiologist, Madras Medical Mission	Member Clinician	Yes	M
Dr. Suma Malini Victor, MBBS, DNB., Consultant Cardiologist, Madras Medical Mission	Member, Clinician	Yes	F
Dr. Chitrasree V, MBBS,DCP Coordinator, Consultant Lab services, Madras Medical Mission	Member, Basic Medical Scientist	Yes	F
Rev.Fr. Ninan Chacko, MA,DPS, Chaplain Theologist, ICVD, Madras Medical Mission	Non-Clinical Member Theologist/Layperson	Yes	M
Mr. Ravi Kumar Paul, LLB Paul & Paul B.A., B.L., Advocates Chennai.	Member Legal Expert	No	M
Dr. C.B Tharani, M.D. Pharmacology	Pharmacologist	No	F
Dr. Philomina Mariados, PhD(Sociology), Dean, College of Health Science, Madras Medical Mission	Member, Lay person	Yes	F

The Committee expects from the Principal Investigator to report the clinical study on annual basis.

It was to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Ethics Committee.

Yours truly,

Signature: _____ **Date:** 17/04/2015

Name: Dr V M Kurian
Title: Member secretary

INSTITUITIONAL ETHICS COMMITTEE
MADRAS MEDICAL MISSION
No. 4 - A, Dr. J.J. NAGAR,
MOGAPPAIR, CHENNAI - 600 037.

APPENDIX – C

PATIENT CONSENT FORM

Respected Sir/ Madam,

I am pursuing my M.sc in Nursing at MMM College of Nursing, Chennai for which I am doing research on effectiveness of cooling gel pack on pain during chest tube removal. I kindly request you to participate and provide the baseline information about you. I also request you to give answer on questions related to your pain perception.

I expect your co-operation while assessing your pain during chest tube removal and also for the application of cooling gel pack around your chest tube site.

I assure you that the details you provided will be used for my research only and will be kept confidential.

The participation is not compulsory and you can withdraw from the study at any time. You can clarify any queries related to this.

I also assure that the intervention provide will not harm you at any cost.

Divya Thankachan Francis
M.Sc Nursing Student
MMM College of Nursing

I would like to participate in the study.

Signature of the Participant:

Date:

APPENDIX – D

TOOL FOR DATA COLLECTION

SECTION A: ASSESSMENT TOOL

SAMPLE NUMBER:

PART 1- DEMOGRAPHIC VARIABLES

1. **Age of the patient in years**

a. 20-30 years

b. 31-40 years

c. 41-50 years

d. 51-60 years

e. 61-70 years

2. **Gender**

a. Male

b. Female

3. **Educational qualification**

a. No formal education

b. Primary school

c. High school

d. Higher Secondary

e. Graduate and above

4. **Occupation**

a. Professional

b. Skilled worker

c. Unemployed

d. Retired

PART II- CLINICAL VARIABLES

1. **Body Mass Index**

a. 18 and less

b. 18.1-23.0

c. 23.1-25.0

d. 25.1-30.0

2. **History of previous surgeries**

a. Minor, if yes (specify)…….

b. Major, if yes (specify)…….

c. Nil

3. **Nature of cardiac surgery undergone**

a. Coronary Artery Bypass Graft- On Pump

b. Coronary Artery Bypass - Off Pump

c. Valve repair surgery

d. Valve replacement surgery

4. **Total number of chest tubes**

a. Two

b. Three

c. Four

5. **Size of chest tube**

a. 28 F

b. 32 F

c. 34 F

6. **Indwell time of chest tubes**

a. Less than 24 hours

b. 24-36 hours

c. 37-48 hours

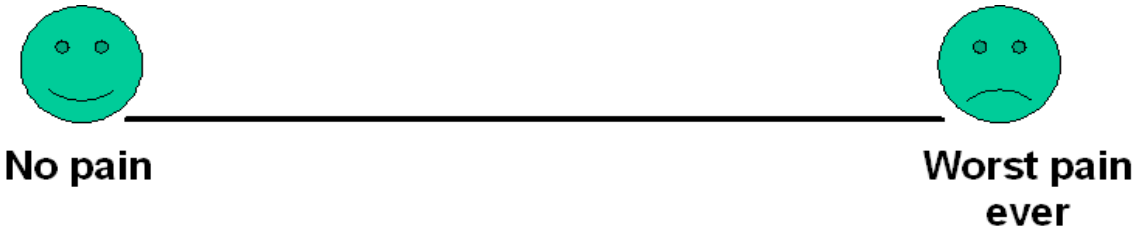
d. More than 48 hours

PART III- MODIFIED COMFORT SCALE TO ASSESS THE LEVEL OF PAIN DISTRESS

S.NO.	INDICATORS	CRITERIA	BASELINE TEST	POST TEST-1	POST TEST-2
OBSERVED PHYSICAL PARAMETERS					
1	ALERTNESS	1. Deeply asleep 2. Lightly asleep 3. Drowsy 4. Fully awake and alert 5. Hyper alert			
2	PHYSICAL MOVEMENT	1. Relaxed 2. Occasional 3. Slight movement 4. Frequent slight movement 5. Vigorous movement of the Torso and head			
3	CALMNESS	1. Calm 2. Slightly anxious 3. Anxious 4. Very Anxious 5. Panicky			
4	FACIAL TENSION	1. Facial muscles totally relaxed 2. Facial muscle tone normal, no evident facial muscle tension 3. Tension evident in some facial muscles 4. Tension is evident throughout facial muscles 5. Facial muscles contorted and grimacing			
OBSERVED PHYSIOLOGICAL PARAMETERS					
5	HEART RATE	1. Heart rate below baseline 2. Consistently at baseline 3. Infrequent elevation of 15% or more above baseline(1-3 during 2min observation) 4. Frequent elevation of 15% or more above baseline(>3during 2min			

S.NO.	INDICATORS	CRITERIA	BASELINE TEST	POST TEST-1	POST TEST-2
		observation) 5. Sustained elevation of 15% or more			
6	RESPIRATORY RATE	1. Respiratory rate below baseline 2. Consistently at baseline 3. Infrequent elevation of 15% or more above baseline (1-3 during 2min observation) 4. Frequent elevation of 15% or more above baseline (>3during 2min observation) 5. Sustained elevation of 15% or more			
7	BLOOD PRESSURE	1. Blood pressure below baseline 2. Consistently at baseline 3. Infrequent elevation of 15% or more above baseline (1-3 during 2min observation) 4. Frequent elevation of 15% or more above baseline (>3during 2min observation) 5. Sustained elevation of 15% or more			
8	SpO_2	1. Spo_2 above baseline 2. Consistently at baseline 3. Infrequent decrease of 15% or more above baseline (1-3 during 2min observation) 4. Frequent decrease of 15% or more above baseline (>3during 2min observation) 5. Sustained decrease of 15% or more			

PART IV- VISUAL ANALOGUE SCALE TO ASSESS THE LEVEL OF PAIN INTENSITY



PRE TEST	POST TEST-1	POST TEST-2

APPENDIX – E

SECTION B: INTERVENTION TOOL

Cryotherapy is the local or general use of low temperatures in medical therapy. The term cryotherapy comes from the Greek word *cryo* meaning cold and *therapy* meaning cure. Cryotherapy in this study refers to the application of cooling gel pack, it is a portable plastic sac filled with a refrigerant gel. They are non-toxic, reusable and non-mutagenous in nature. Gel packs are made of hydroxyethyl cellolose, sodium polyacrylate or vinyl- coated silica gel. The cooling gel packs are available in the standard durable laminated plastic pouch made of "no-sweat" paper material to protect against condensation touching the product. The physiologic effects of cooling gel packs include immediate vasoconstriction with reflexive vasodilation, decreased local metabolism and enzymatic activity, and decreased oxygen demand. Cold application decreases muscle spindle fiber activity and slows nerve conduction velocity; therefore it is often used to decrease spasticity and muscle guarding. It is commonly used to alleviate the pain of minor injuries, as well as decrease muscle soreness. The use of cooling gel packs in treatment decreases the blood flow most rapidly at the beginning of the cooling period, this occurs as a result of vasoconstriction, the initial reflex sympathetic activity. The cooling gel packs are popular modality for the treatment of injuries and muscle repair. The effectiveness of cooling gel pack is scientifically proven to reduce pain and promote recovery for soft tissue injury. The first cold gel trial in the world was carried out in Kuopio university in cooperation with university hospitals. The study with cooling gel was conducted by Dr. Olavi Airaksinen and the short report of the study had been published in the American Academy of physical medicine & rehabilitation. The clinical trial showed that the effectiveness of cooling gel packs begins immediately after the application and decreases pain by half.

The blue cooling gel packs which were used in this study is capable of maintaining the temperature between +2 to+8°C. For cryotherapy the cooling gel packs used in this study were placed in the refrigerator for up to an hour, to achieve the desired cooling effect. The patient was made to lie down in supine position with the head end elevated to 30°**.** The cooling gel packs used in this study were flexible and it confined

well to body parts especially around the chest tube as they were also available in horse shoe shape so that they could cover around tubes easily. This leads to an effective cooling of the tissues around the chest tube site. Sterile gauze was used between the cooling gel packs and the skin surface to prevent frostbite. It was applied around the chest tube for a period of 15 minutes, later which the cooling gel packs were removed and the chest tube was removed according to the hospital routine.

These cooling gel packs as they were reusable, the researcher applied it around the chest tube insertion site for the patients wrapped with sterile gauze. It was sterilized each time after its use by ethylene oxide sterilizer before using it for another patient. Ethylene Oxide (EtO) sterilization is mainly used to sterilize medical and pharmaceutical products that cannot support conventional high temperature steam sterilization - such as devices that incorporate electronic components, plastic packaging or plastic containers. Hence the researcher had maintained the sterility of the cooling gel packs each time before its application thus preventing any chance for infection or cross infection.

APPENDIX – F

LETTER SEEKING EXPERTS OPINION AND SUGGESTION FOR THE CONTENT VALIDITY TOOL

FROM

Mrs. Divya Thankachan Francis
1st Year M.Sc. Nursing
MMM College of Nursing
Mogappair West
Chennai – 60.

TO

_____
_____
_____

Forwarded Through

The Principal
MMM College of Nursing
Mogappair West
Chennai – 60.

Respected Sir\Madam,

Sub: Expert opinion for content validation of research tool.

I, Ms.Divya T Francis, 1st year M. Sc. Nursing student (Medical and Surgical Nursing) of MMM College of Nursing, request your good self, if you could kindly accept to validate my research tool on topic "**Effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected hospital, Chennai."**

I would be obliged if you would kindly affirm your acceptance to the undersigned with your valuable suggestion on this topic. I shall send details of my study along with the research tool.

Thanking you in anticipation.

Yours Sincerely

Ms. Divya Thankachan Francis

LIST OF ExPERTS FOR CONTENT VALIDITY

1. **Dr. Anbarasu Mohanraj**
   Senior Cardio Vascular Surgeon,
   Dept of Cardio Thoracic Surgery.
   Madras Medical Mission Hospital.

2. **Dr. Kannakarajan .N**
   Senior Anesthetist,
   Dept of Cardio Thoracic Surgery,
   Madras Medical Mission Hospital.

3. **Mrs. Annie Raja**
   Principal,
   St. Isabel's College of Nursing,
   Chennai.

4. **Prof. Mrs.Aswathi K.V.**
   Principal,
   St. Thomas College of Nursing,
   Chethipuzha, Chaganacherry, Kerala.

5. **Mrs. Kavitha**
   Asst Professor,
   MIOT College of Nursing,
   Chennai.

CONTENT VALIDITY CERTIFICATE

This is to certify that , **MS. DIVYA THANKACHAN FRANCIS,** student studying M.Sc(Nursing) I year at MMM College of Nursing, Chennai -91, affiliated to Dr.MGR.Medical University, Tamil Nadu her data collection tool on the topic , **" A true experimental study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai** "is validated and suggested the necessary changes to execute.

Signature of the expert

DR. ANBARASU MOHANRAJ

Date: 4-2-2015

Place: CHENNAI

Designation and Address

Dr. ANBARASU MOHANRAJ, MS.,DNB.,MCh.
Reg. No: 55476
Senior Consultant-Cardiothoracic Surgeon
The Madras Medical Mission
Chennai-600 037.

CONTENT VALIDITY CERTIFICATE

This is to certify that **Ms.Divya Thankachan Francis**, M.Sc. (Nursing) at MMM College of Nursing, affiliated to The Tamil Nadu Dr.MG.R. Medical University whose data collection tool on the topic, **"Effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected hospital, Chennai"** is being validated by me and I have suggested the necessary changes to execute.

N. Kanagarajan

Signature of the expert

Date: 23/12/15

Designation and address

Place: Chennai

Dr. N. KANAGARAJAN, MD., PDCC.
Reg. No: 53618
Senior Consultant - Anaesthesia
The Madras Medical Mission
Chennai-600 037.

CONTENT VALIDITY CERTIFICATE

This is to certify that , **MS. DIVYA THANKACHAN FRANCIS,** student studying M.Sc(Nursing) I year at MMM College of Nursing, Chennai -91, affiliated to Dr.MGR.Medical University, Tamil Nadu her data collection tool on the topic , **" A true experimental study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai "**is validated and suggested the necessary changes to execute.

Annie

Signature of the expert

PRINCIPAL
ST. ISABEL'S COLLEGE OF NURSING
49, Oliver Road,
Mylapore, Chennai-600 004.

Date: 06.02.2015

Place: Chennai

Designation and Address

Annie Raja
Principal.
St. Isabel's College of
Nursing,
49, Oliver Road
Chennai
600004

CONTENT VALIDITY CERTIFICATE

This is to certify that , **MS. DIVYA THANKACHAN FRANCIS,** student studying M.Sc(Nursing) I year at MMM College of Nursing, Chennai -91, affiliated to Dr.MGR.Medical University, Tamil Nadu her data collection tool on the topic , **" A true experimental study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai "**is validated and suggested the necessary changes to execute.

ST. THOMAS COLLEGE OF NURSING * CHANGANACHERRY * P.O. KURISUMMOODU * CHETHIPUZHA *

Signature of the expert

Date: 12/2/2015

Place: Chethipuzha.

Designation and Address

PRINCIPAL
ST. THOMAS COLLEGE OF NURSING
CHETHIPUZHA
CHANGANACHERRY - 686 104

CONTENT VALIDITY CERTIFICATE

This is to certify that , **MS. DIVYA THANKACHAN FRANCIS,** student studying M.Sc(Nursing) I year at MMM College of Nursing, Chennai -91, affiliated to Dr.MGR.Medical University, Tamil Nadu her data collection tool on the topic , " **A true experimental study to assess the effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected setting in Chennai** "is validated and suggested the necessary changes to execute.

Signature of the expert

M. KAVITHA.

ASST PROFESSOR.

Designation and Address

MIOT COLLEGE OF NURSING
4/112 Mount poonamalle Road
Manapakkam
Chennai - 89.

Date: 8/1/2015

Place: CHENNAI.

APPENDIX – G

CERTIFICATE OF ENGLISH EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the study executed by Ms.Divya Thankachan Francis, M.Sc. Nursing II year student in MMM College of Nursing on the topic **"Effectiveness of cryotherapy on procedural pain among the cardiac post operative patients at a selected hospital, Chennai"** affiliated to The Tamil Nadu Dr.M.G.R. Medical University, Chennai is edited for English language appropriateness by Fr. Moncy Kaleekal MA,M.Ed

The words used in the study submitted was edited by me and found to be correct and appropriate.

21/12/15

FR. MONCY KALEECKAL M.A., M.Ed.,
PRINCIPAL
SACRED HEART MATRIC. HIGHER SECONDARY SCHOOL
MARIA NAGAR, PADI, CHENNAI - 600 050.

SACRED HEART MATRIC. HIGHER SECONDARY SCHOOL
MARIA NAGAR, PADI,
CHENNAI - 600 050.

APPENDIX – H

PLAGIARISM REPORT

"Divya T Francis.docx"

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Size:	162334 words
Registered to:	DR. ROSALINE RACHEL
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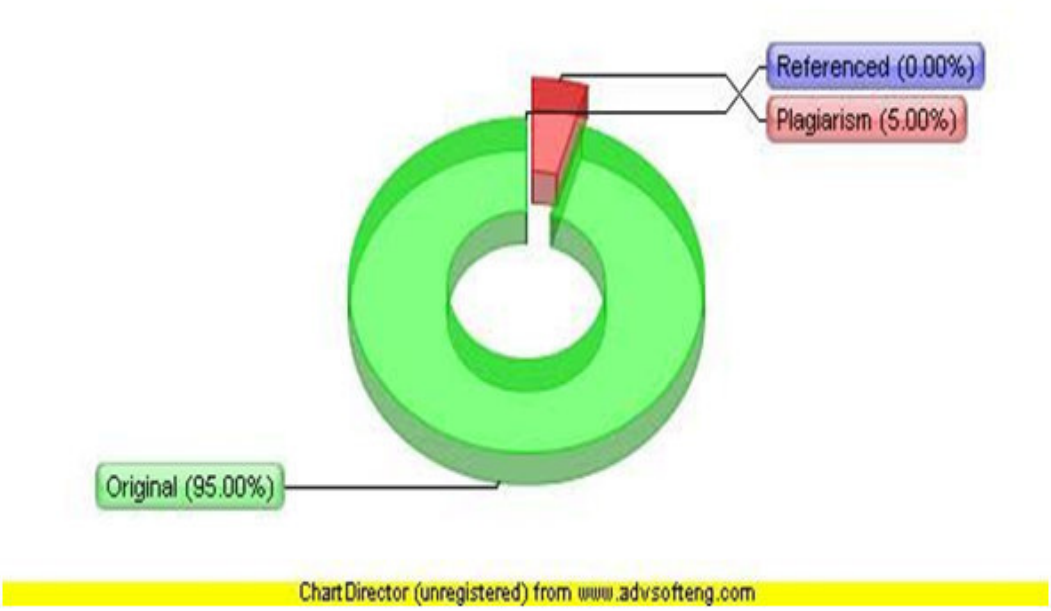

APPENDIX – I

PHOTOGRAPHS


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